

# SEARCH REQUEST FORM

Scientific and Technical Information Center

Requester's Full Name: MIKE PEFFLEY Examiner #: 71301 Date: 9/10/01  
Art Unit: 3734 Phone Number 308-4305 Serial Number: 107728101  
Mail Box and Bldg/Room Location: CP2 4E10 Results Format Preferred (circle) PAPER DISK E-MAIL

If more than one search is submitted, please prioritize searches in order of need.  
\*\*\*\*\*

Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc, if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.

Title of Invention: Preformed catheter set for use with a linear ablation system  
Inventors (please provide full names): produce ablation lines in the left and right atria for treatment of atrial fibrillation

Earliest Priority Filing Date: 2/20/2003

\*For Sequence Searches Only\* Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.

Inventors: Gregory K. Feld  
Theodore C. Ormsby  
Ming-Fan Law  
George L. Leung

See claim 10 attached

PG PUB/2004-0167510

STAFF USE ONLY		Type of Search	Vendors and cost where applicable
Searcher: <u>Enclm Danner</u>	NA Sequence (#) _____	STN _____	
Searcher Phone #: <u>305 8587</u>	AA Sequence (#) _____	Dialog <input checked="" type="checkbox"/> <u>1106 66</u>	
Searcher Location: <u>CP2 2 C8</u>	Structure (#) _____	Questel/Orbit _____	
Date Searcher Picked Up: <u>9/16/04 (315P)</u>	Bibliographic <input checked="" type="checkbox"/>	Dr.Link _____	
Date Completed: <u>9/17/04 345P</u>	Litigation _____	Lexis/Nexis _____	
Searcher Prep & Review Time: <u>2:00 am</u>	Fulltext <input checked="" type="checkbox"/>	Sequence Systems _____	
Clerical Prep Time: <u>Q</u>	Patent Family _____	WWW/Internet <input checked="" type="checkbox"/> <u>SciBus/SciSearch</u>	
Online Time: <u>2:00 am</u>	Other _____	Other (specify) <u>DIRECT</u>	



# STIC Search Report

## EIC 3700

STIC Database Tracking Number: 132209

TO: Mike Peffley  
Location: cp2 4e10  
Art Unit: 3739  
Friday, September 17, 2004

Case Serial Number: 10/772861

From: Emory Damron  
Location: EIC 3700  
CP2-2C08  
Phone: 305-8587

[Emory.Damron@uspto.gov](mailto:Emory.Damron@uspto.gov)

### Search Notes

Dear Mike,

Please find below an inventor search in the bibliographic and full-text foreign patent files, as well as keyword searches in the patent and non-patent literature files, both bibliographic and full text.

References of potential pertinence have been tagged, but please review all the packets in case you like something I didn't.

In addition to searching on Dialog, I also EPO/JPO/Derwent, Scirus and ScienceDirect.

The preponderance of the better art is in the full text patent literature packet; those references which are particularly good have commentary on them.

Please contact me if I can refocus or expand any aspect of this case, and please take a moment to provide any feedback (on the form provided) so EIC 3700 may better serve your needs.

Sincerely,

Emory Damron

Technical Information Specialist

EIC 3700, US Patent & Trademark Office

Phone: (703) 305-8587/ Fax: (703) 306-5915

[Emory.damron@uspto.gov](mailto:Emory.damron@uspto.gov)





# STIC Search Results Feedback Form

**EIC 3700**

Questions about the scope or the results of the search? Contact *the EIC searcher or contact:*

John Sims, EIC 3700 Team Leader  
308-4836, CP2-2C08

## Voluntary Results Feedback Form

➤ I am an examiner in Workgroup: 3739 Example: 3730

➤ Relevant prior art **found**, search results used as follows:

- ☐ 102 rejection
- ☐ 103 rejection
- ☐ Cited as being of interest.
- ☐ Helped examiner better understand the invention.
- ☐ Helped examiner better understand the state of the art in their technology.

Types of relevant prior art found:

- ☐ Foreign Patent(s)
- ☐ Non-Patent Literature  
(journal articles, conference proceedings, new product announcements etc.)

➤ Relevant prior art **not found**:

- ☐ Results verified the lack of relevant prior art (helped determine patentability).
- ☐ Results were not useful in determining patentability or understanding the invention.

Comments:

Drop off or send completed forms to STIC/EIC3700 CP2 2C08



Set	Items	Description
S1	93	AU=(FELD G? OR FELD, G? OR ORMSBY T? OR ORMSBY, T? OR LAW - M? OR LAW, M? OR LAW MF OR LAW, MF OR LEUNG G? OR LEUNG, G?)
S2	0	GREG?(2N)FELD OR (THEODORE OR TED) (2N)ORMSBY OR MING?(2N)L- AW OR GEORGE(2N)LEUNG
S3	5522	(FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLU- TTER?) AND (ATRIU? OR ATRIA? OR CARDI?)
S4	248095	IC=A61B?
S5	4	S1:S2 AND S3
S6	19	S1:S2 AND S4
S7	19	S5:S6
S8	19	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 347:JAPIO Nov 1976-2004/May(Updated 040903)

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File 350:Derwent WPIX 1963-2004/UD,UM &UP=200459

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8/3,K/1 (Item 1 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015716698 \*\*Image available\*\*

WPI Acc No: 2003-778898/200373

Related WPI Acc No: 1996-476776; 1997-051698; 1997-297829; 1997-297832;  
1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;  
1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-113443; 2002-121081; 2002-147711;  
2002-163510; 2002-170989; 2002-206288; 2002-214577; 2002-370567;  
2002-636083; 2002-691219; 2003-015692; 2003-028464; 2003-254801;  
2003-330499; 2003-361993; 2003-417299; 2003-419759; 2003-421185;  
2003-567867; 2003-576879; 2003-707520; 2003-755934; 2003-801399;  
2003-895627; 2003-898307; 2003-902058; 2004-167062; 2004-167544;  
2004-224783; 2004-238519; 2004-327350

XRAM Acc No: C03-214343

XRPX Acc No: N03-624259

Electrosurgical probe, for ablating cartilage tissue from synovial joint,  
comprises shaft with distal end and shaft proximal end, electrically  
insulating electrode support, and electrode array

Patent Assignee: ARTHROCARE CORP (ARTH-N)

Inventor: DAVISON T S; ORMSBY T C; WOLOSZKO J; DAVISON P O

Number of Countries: 102 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200368311	A2	20030821	WO 2003US4689	A	20030213	200373 B
US 20030225403	A1	20031204	US 2000210567	P	20000609	200380
			US 2000233345	P	20000918	
			US 2000709035	A	20001108	
			US 2001758403	A	20010110	
			US 2001766168	A	20010119	
			US 2001836940	A	20010417	
			US 2002357570	P	20020213	
			US 2003367608	A	20030213	
AU 2003215263	A1	20030904	AU 2003215263	A	20030213	200428

Priority Applications (No Type Date): US 2002357570 P 20020213; US  
2000210567 P 20000609; US 2000233345 P 20000918; US 2000709035 A 20001108  
; US 2001758403 A 20010110; US 2001766168 A 20010119; US 2001836940 A  
20010417; US 2003367608 A 20030213

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200368311 A2 E 208 A61N-000/00

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SC SD SE SG SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU  
ZA ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB  
GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PT SD SE SI SK SL SZ TR TZ UG  
ZM ZW

US 20030225403 A1 A61B-018/14 Provisional application US 2000210567

Provisional application US 2000233345

CIP of application US 2000709035

CIP of application US 2001758403

CIP of application US 2001766168  
CIP of application US 2001836940  
Provisional application US 2002357570  
CIP of patent US 6589237  
Based on patent WO 200368311  
AU 2003215263 A1 A61N-000/00

...Inventor: ORMSBY T C  
International Patent Class (Main): A61B-018/14 ...

8/3,K/2 (Item 2 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015514732 \*\*Image available\*\*

WPI Acc No: 2003-576879/200354

Related WPI Acc No: 1996-476776; 1997-051698; 1997-297829; 1997-297832;  
1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;  
1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-113443; 2002-121081; 2002-147711;  
2002-163510; 2002-206288; 2002-214577; 2002-370567; 2002-636083;  
2002-691219; 2003-015692; 2003-028464; 2003-254801; 2003-330499;  
2003-361993; 2003-417299; 2003-419759; 2003-421185; 2003-567867;  
2003-707520; 2003-755934; 2003-778898; 2003-801399; 2003-895627;  
2003-898307; 2003-902058; 2004-167062; 2004-167544; 2004-224783;  
2004-238519; 2004-327350

XRAM Acc No: C03-155791

XRPX Acc No: N03-458568

Electrosurgical probe e.g. for ablating tissue of patient, has shaft  
whose distal end adopts closed or open configuration, in order to clamp  
or release tissue, by pivoting return electrode arranged at distal end

Patent Assignee: ARTHROCARE CORP (ARTH-N)

Inventor: ORMSBY T C ; TSUJI C; WOLOSZKO J

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030097126	A1	20030522	US 9359681	A	19930510	200354 B
			WO 94US5168	A	19940510	
			US 95485219	A	19950607	
			US 9762996	P	19971023	
			US 97990374	A	19971215	
			US 9841934	A	19980313	
			US 2000182751	P	20000216	
			US 2001780745	A	20010209	
			US 2001839427	A	20010420	

Priority Applications (No Type Date): US 2001839427 A 20010420; US 9359681  
A 19930510; WO 94US5168 A 19940510; US 95485219 A 19950607; US 9762996 P  
19971023; US 97990374 A 19971215; US 9841934 A 19980313; US 2000182751 P  
20000216; US 2001780745 A 20010209

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20030097126	A1		84	A61B-018/14	CIP of application US 9359681 CIP of application WO 94US5168 CIP of application US 95485219 Provisional application US 9762996 CIP of application US 97990374

CIP of application US 9841934  
Provisional application US 2000182751  
CIP of application US 2001780745  
CIP of patent US 5697281  
CIP of patent US 6109268  
CIP of patent US 6391025

Inventor: ORMSBY T C ...

International Patent Class (Main): A61B-018/14

8/3,K/3 (Item 3 from file: 350)

DIALOG(R)File 350:Derwent WPIX

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014327008 \*\*Image available\*\*

WPI Acc No: 2002-147711/200219

Related WPI Acc No: 1993-242930; 1995-006306; 1995-206153; 1996-476776;

1997-051698; 1997-297829; 1997-297832; 1998-120425; 1998-120493;  
1998-530718; 1999-059988; 1999-130298; 1999-179878; 1999-214453;  
1999-277173; 1999-312540; 1999-312547; 1999-385169; 1999-395076;  
1999-518494; 1999-580571; 2000-062120; 2000-195426; 2000-204827;  
2000-237402; 2000-255603; 2000-422843; 2000-531792; 2000-542909;  
2000-587596; 2001-049631; 2001-069745; 2001-070821; 2001-225913;  
2001-343206; 2001-424601; 2001-522540; 2001-646987; 2002-082230;  
2002-113415; 2002-113443; 2002-121081; 2002-163510; 2002-170989;  
2002-206288; 2002-214577; 2002-370567; 2002-636083; 2002-691219;  
2003-015692; 2003-028464; 2003-246251; 2003-254801; 2003-330499;  
2003-361993; 2003-417299; 2003-419759; 2003-421185; 2003-567867;  
2003-576879; 2003-707520; 2003-755934; 2003-778898; 2003-801399;  
2003-895627; 2003-898307; 2003-901104; 2003-902058; 2004-167062;  
2004-167544; 2004-224783; 2004-238519; 2004-327350

XRPX Acc No: N02-111982

**Electrosurgical probe for use in arthroscopic surgery, plastic surgery,  
has working zones with mutually spaced aspiration ports having different  
aspiration rates**

Patent Assignee: ARTHROCARE CORP (ARTH-N); DAVISON T S (DAVI-I); ORMSBY T C  
(ORMS-I); WILLINK C L (WILL-I)

Inventor: DAVISON T S; EGGERS P E; HOVDA D C; MASTERSON S P; ORMSBY T C ;  
THAPLIYAL H V; WILLINK C L; WOLOSZKO J; DAVISON P O; MASTERSON S

Number of Countries: 095 Number of Patents: 009

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200195819	A1	20011220	WO 2001US16006	A	20010516	200219 B
US 20020026186	A1	20020228	US 95485219	A	19950607	200220
			US 97990374	A	19971215	
			US 9810382	A	19980121	
			US 98197013	A	19981120	
			US 2000210567	P	20000609	
			US 2000233345	P	20000918	
			US 2001758403	A	20010110	
AU 200161726	A	20011224	AU 200161726	A	20010516	200227
US 20020052600	A1	20020502	US 9810382	A	19980121	200234
			US 98197013	A	19981120	
			US 2000210567	P	20000609	
			US 2000233345	P	20000918	
			US 2000709035	A	20001108	
			US 2001758403	A	20010110	
			US 2001766168	A	20010119	
			US 2001766169	A	20010119	
			US 2001836940	A	20010417	
EP 1289438	A1	20030312	EP 2001935650	A	20010516	200320

US 6589237	B2	20030708	WO 2001US16006	A	20010516	
			US 9359681	A	19930510	200353
			WO 94US5168	A	19940510	
			US 95485219	A	19950607	
			US 9762996	P	19971023	
			US 97990374	A	19971215	
			US 9810382	A	19980121	
			US 98197013	A	19981120	
			US 2000210567	P	20000609	
			US 2000233345	P	20000918	
			US 2001766168	A	20010119	
US 20030225403	A1	20031204	US 2000210567	P	20000609	200380
			US 2000233345	P	20000918	
			US 2000709035	A	20001108	
			US 2001758403	A	20010110	
			US 2001766168	A	20010119	
			US 2001836940	A	20010417	
			US 2002357570	P	20020213	
			US 2003367608	A	20030213	
US 6746447	B2	20040608	US 9359681	A	19930510	200437
			WO 94US5168	A	19940510	
			US 95485219	A	19950607	
			US 97990374	A	19971215	
			US 9810382	A	19980121	
			US 98197013	A	19981120	
			US 2000210567	P	20000609	
			US 2000233345	P	20000918	
			US 2000709035	A	20001108	
			US 2001766168	A	20010129	
			US 2001836940	A	20010417	
US 20040153057	A1	20040805	US 98197013	A	19981120	200452
			US 2001836940	A	20010417	
			US 2003713643	A	20031113	

Priority Applications (No Type Date): US 2001836940 A 20010417; US 2000210567 P 20000609; US 2000233345 P 20000918; US 2000709035 A 20001108; US 2001758403 A 20010110; US 2001766168 A 20010119; US 95485219 A 19950607; US 97990374 A 19971215; US 9810382 A 19980121; US 98197013 A 19981120; US 2001766169 A 20010119; US 9359681 A 19930510; WO 94US5168 A 19940510; US 9762996 P 19971023; US 2002357570 P 20020213; US 2003367608 A 20030213; US 2003713643 A 20031113

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200195819	A1	E	201	A61B-018/14	
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Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

US 20020026186	A1
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CIP of application US 95485219

CIP of application US 97990374

CIP of application US 9810382

CIP of application US 98197013

Provisional application US 2000210567

Provisional application US 2000233345

CIP of patent US 5697281

CIP of patent US 6109268

CIP of patent US 6190381

CIP of patent US 6296638

AU 200161726	A
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Based on patent WO 200195819

US 20020052600 A1	A61B-018/14	CIP of application US 9810382 CIP of application US 98197013 Provisional application US 2000210567 Provisional application US 2000233345 CIP of application US 2000709035 CIP of application US 2001758403 CIP of application US 2001766168 CIP of application US 2001766169
EP 1289438 A1 E	A61B-018/14	Based on patent WO 200195819
Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR		
US 6589237 B2	A61B-018/14	CIP of application US 9359681 CIP of application WO 94US5168 CIP of application US 95485219 Provisional application US 9762996 CIP of application US 97990374 CIP of application US 9810382 CIP of application US 98197013 Provisional application US 2000210567 Provisional application US 2000233345 CIP of patent US 5697281 CIP of patent US 5697909 CIP of patent US 6109268 CIP of patent US 6190381 CIP of patent US 6296638
US 20030225403 A1	A61B-018/14	Provisional application US 2000210567  Provisional application US 2000233345 CIP of application US 2000709035 CIP of application US 2001758403 CIP of application US 2001766168 CIP of application US 2001836940 Provisional application US 2002357570 CIP of patent US 6589237
US 6746447 B2	A61B-018/14	CIP of application US 9359681 CIP of application WO 94US5168 CIP of application US 95485219 CIP of application US 97990374 CIP of application US 9810382 CIP of application US 98197013 Provisional application US 2000210567 Provisional application US 2000233345 CIP of application US 2000709035 CIP of application US 2001766168 CIP of patent US 5697281 CIP of patent US 5697909 CIP of patent US 6190381 CIP of patent US 6296638
US 20040153057 A1	A61B-018/14	CIP of application US 98197013 Cont of application US 2001836940 CIP of patent US 6296638 Cont of patent US 6746447

...Inventor: ORMSBY T C  
International Patent Class (Main): A61B-018/14

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8/3,K/4 (Item 4 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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015269570 \*\*Image available\*\*

WPI Acc No: 2003-330499/200331

Related WPI Acc No: 1999-312540; 1999-395076; 2000-062120; 2000-237402;  
2000-587596; 2001-049631; 2001-070821; 2001-225913; 2001-343206;  
2001-522540; 2001-646987; 2002-082230; 2002-113443; 2002-147711;  
2002-163510; 2002-206288; 2002-214577; 2002-370567; 2002-636083;  
2002-691219; 2003-015692; 2003-028464; 2003-254801; 2003-361993;  
2003-417299; 2003-419759; 2003-421185; 2003-567867; 2003-576879;  
2003-755934; 2003-778898; 2003-801399; 2003-895627; 2003-898307;  
2003-901104; 2004-167062; 2004-167544; 2004-224783; 2004-238519;  
2004-327350

XRFX Acc No: N03-264604

Active electrode for electro surgical apparatus has distal electrode head  
which is formed by making void in distal portion of filament and void is  
shaped to form loop

Patent Assignee: ELLSBERRY M (ELLS-I); HOVDA D C (HOVD-I); ORMSBY T C  
(ORMS-I); WOLOSZKO J (WOLO-I)

Inventor: ELLSBERRY M; HOVDA D C; ORMSBY T C ; WOLOSZKO J

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030014047	A1	20030116	US 95485219	A	19950607	200331 B
			US 96690159	A	19960718	
			US 97990374	A	19971215	
			US 9826851	A	19980220	
			US 9854323	A	19980402	
			US 99268616	A	19990315	
			US 99295687	A	19990421	
			WO 2000US13706	A	20000517	
			US 2000224107	P	20000809	
			US 2000676194	A	20000928	
			US 2001299082	P	20010618	
			US 2002175555	A	20020618	

Priority Applications (No Type Date): US 2002175555 A 20020618; US 95485219  
A 19950607; US 96690159 A 19960718; US 97990374 A 19971215; US 9826851 A  
19980220; US 9854323 A 19980402; US 99268616 A 19990315; US 99295687 A  
19990421; WO 2000US13706 A 20000517; US 2000224107 P 20000809; US  
2000676194 A 20000928; US 2001299082 P 20010618

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20030014047	A1		103	A61B-018/14	CIP of application US 95485219
					CIP of application US 96690159
					CIP of application US 97990374
					CIP of application US 9826851
					CIP of application US 9854323
					CIP of application US 99268616
					CIP of application US 99295687
					CIP of application WO 2000US13706
					Provisional application US 2000224107
					CIP of application US 2000676194
					Provisional application US 2001299082
					CIP of patent US 5697281
					CIP of patent US 5902272
					CIP of patent US 6063079
					CIP of patent US 6109268
					CIP of patent US 6159208
					CIP of patent US 6203542
					CIP of patent US 6277112

...Inventor: ORMSBY T C

International Patent Class (Main): A61B-018/14

8/3,K/5 (Item 5 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014385585 \*\*Image available\*\*

WPI Acc No: 2002-206288/200226

Related WPI Acc No: 1993-242930; 1995-006306; 1995-206153; 1996-476776;  
1997-051698; 1997-297829; 1997-297832; 1998-120425; 1998-120493;  
1998-530718; 1999-059988; 1999-130298; 1999-179878; 1999-214453;  
1999-277173; 1999-312540; 1999-312547; 1999-385169; 1999-395076;  
1999-518494; 1999-580571; 2000-062120; 2000-195426; 2000-204827;  
2000-237402; 2000-255603; 2000-422843; 2000-531792; 2000-542909;  
2000-587596; 2001-049631; 2001-069745; 2001-070821; 2001-225913;  
2001-343206; 2001-424601; 2001-522540; 2001-646987; 2002-082230;  
2002-113415; 2002-113443; 2002-121081; 2002-147711; 2002-163510;  
2002-170989; 2002-214577; 2002-370567; 2002-636083; 2002-691219;  
2003-015692; 2003-028464; 2003-254801; 2003-330499; 2003-361993;  
2003-417299; 2003-419759; 2003-421185; 2003-567867; 2003-576879;  
2003-707520; 2003-755934; 2003-778898; 2003-801399; 2003-895627;  
2003-898307; 2003-901104; 2003-902058; 2004-167062; 2004-167544;  
2004-224783; 2004-238519; 2004-327350

XRFX Acc No: N02-157102

**Spinal disorder treatment apparatus for advancing and retarding medical instrument within introducer device to area of vertebra disc intended for treatment**

Patent Assignee: ARTHROCARE CORP (ARTH-N); ARTHRO CARE CORP (ARTH-N)

Inventor: EGGERS P E; HOVDA D C; MARTINI B; ORMSBY T C; QUACKENBUSH J J;  
SHARPS L; THAPLIYAL H V; WOLOSZKO J

Number of Countries: 095 Number of Patents: 005

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200211635	A1	20020214	WO 2001US15728	A	20010515	200226 B
AU 200161637	A	20020218	AU 200161637	A	20010515	200244
EP 1309282	A1	20030514	EP 2001935554	A	20010515	200333
			WO 2001US15728	A	20010515	
US 6602248	B1	20030805	US 95485219	A	19950607	200353
			US 96690159	A	19960718	
			US 97990374	A	19971215	
			US 9826851	A	19980220	
			US 9854323	A	19980402	
			US 99268616	A	19990315	
			US 99295687	A	19990421	
			US 99316472	A	19990521	
			WO 2000US13706	A	20000517	
			US 2000224107	P	20000809	
			US 2000676194	A	20000928	
JP 2004505663	W	20040226	WO 2001US15728	A	20010515	200416
			JP 2002516975	A	20010515	

Priority Applications (No Type Date): US 2000679394 A 20001003; US  
2000224107 P 20000809; US 2000676194 A 20000928; US 95485219 A 19950607;  
US 96690159 A 19960718; US 97990374 A 19971215; US 9826851 A 19980220; US  
9854323 A 19980402; US 99268616 A 19990315; US 99295687 A 19990421; US  
99316472 A 19990521; WO 2000US13706 A 20000517

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200211635 A1 E 141 A61B-018/14

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP  
KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT

RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW  
 Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR  
 IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW  
 AU 200161637 A A61B-018/14 Based on patent WO 200211635  
 EP 1309282 A1 E A61B-018/14 Based on patent WO 200211635  
 Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT  
 LI LT LU LV MC MK NL PT RO SE SI TR  
 US 6602248 B1 A61B-018/14 CIP of application US 95485219  
 CIP of application US 96690159  
 CIP of application US 97990374  
 CIP of application US 9826851  
 CIP of application US 9854323  
 CIP of application US 99268616  
 CIP of application US 99295687  
 Cont of application US 99316472  
 CIP of application WO 2000US13706  
 Provisional application US 2000224107  
 JP 2004505663 W 202 A61B-017/56 Based on patent WO 200211635  
 ...Inventor: ORMSBY T C  
 International Patent Class (Main): A61B-017/56 ...

... A61B-018/14  
 International Patent Class (Additional): A61B-018/04

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8/3,K/6 (Item 6 from file: 350)  
 DIALOG(R)File 350:Derwent WPIX  
 (c) 2004 Thomson Derwent. All rts. reserv.

016339737 \*\*Image available\*\*  
 WPI Acc No: 2004-497634/200447  
 Related WPI Acc No: 2000-532552; 2004-118192  
 XRPX Acc No: N04-392908

**Biological tissue ablating method for body vessel e.g. atrium , involves  
 sensing reflected and forward RF energy pulses and adjusting output  
 frequency of RF pulses to match transmission line impedance with load  
 impedance**

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I)  
 Inventor: LAW M ; LEUNG G L ; ORMSBY T C  
 Number of Countries: 001 Number of Patents: 001  
 Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20040106917	A1	20040603	US 98211188	A	19981214	200447 B
			US 99459058	A	19991211	
			US 2002306757	A	20021127	
			US 2003637325	A	20030808	

Priority Applications (No Type Date): US 2003637325 A 20030808; US 98211188  
 A 19981214; US 99459058 A 19991211; US 2002306757 A 20021127

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20040106917	A1	11	A61B-018/18	CIP of application US 98211188
				CIP of application US 99459058
				CIP of application US 2002306757
				CIP of patent US 6190382
				CIP of patent US 6663625

**Biological tissue ablating method for body vessel e.g. atrium , involves  
 sensing reflected and forward RF energy pulses and adjusting output  
 frequency of RF pulses...**

Inventor: LAW M ...



... LEUNG G L ...

... ORMSBY T C

Abstract (Basic):

... for ablating a biological tissue (claimed) and occlusion of a body vessel e.g. an atrium of a patient and liquid-filled lumens of animals such as heart, liver and vessels of a human for the treatment of cardiac arrhythmia and solid tumor...

...Title Terms: ATRIUM ;

International Patent Class (Main): A61B-018/18

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8/3,K/7 (Item 7 from file: 350)

DIALOG(R)File 350:Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

015960351 \*\*Image available\*\*

WPI Acc No: 2004-118192/200412

Related WPI Acc No: 2000-532552; 2004-497634

XRPX Acc No: N04-094382

Body tissue ablation method involves deploying radio frequency antenna out of catheter at target ablation site, by sliding hollow cable over monorail guide

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I)

Inventor: LAW M ; LEUNG G L ; ORMSBY T C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6663625	B1	20031216	US 98211188	A	19981214	200412 B
			US 99459058	A	19991211	

Priority Applications (No Type Date): US 99459058 A 19991211; US 98211188 A 19981214

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 6663625	B1	18	A61B-018/18	CIP of application US 98211188 CIP of patent US 6190382

Inventor: LAW M ...

... LEUNG G L ...

... ORMSBY T C

Abstract (Basic):

... For ablating biological tissue within body vessel of patient, for treatment of cardiac arrhythmias .

International Patent Class (Main): A61B-018/18

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8/3,K/8 (Item 8 from file: 350)

DIALOG(R)File 350:Derwent WPIX

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015505720 \*\*Image available\*\*

WPI Acc No: 2003-567867/200353

Related WPI Acc No: 1996-476776; 1997-051698; 1997-297829; 1997-297832; 1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;

1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-113443; 2002-121081; 2002-147711;  
2002-163510; 2002-170989; 2002-206288; 2002-214577; 2002-370567;  
2002-636083; 2002-691219; 2003-015692; 2003-028464; 2003-254801;  
2003-330499; 2003-361993; 2003-417299; 2003-419759; 2003-421185;  
2003-576879; 2003-707520; 2003-755934; 2003-778898; 2003-801399;  
2003-895627; 2003-898307; 2003-902058; 2004-167062; 2004-167544;  
2004-224783; 2004-238519; 2004-327350

XRAM Acc No: C03-153184

XRPX Acc No: N03-451518

Electrosurgical probe for removing tissue such as sinus tissue, adipose tissue in joint, has active electrode assembly which includes active electrode screen and electrode support having treatment surface and flow protectors

Patent Assignee: ARTHROCARE CORP (ARTH-N)

Inventor: DAHLA R H; DAVISON T S; ORMSBY T C ; WOLOSZKO J

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030097129	A1	20030522	US 9810382	A	19980121	200353 B
			US 98197013	A	19981120	
			US 2000210567	P	20000609	
			US 2000233345	P	20000918	
			US 2000709035	A	20001108	
			US 2001758403	A	20010110	
			US 2001766168	A	20010119	
			US 2001836940	A	20010417	
			US 2001326516	P	20011002	
			US 2003264308	A	20030121	

Priority Applications (No Type Date): US 2003264308 A 20030121; US 9810382 A 19980121; US 98197013 A 19981120; US 2000210567 P 20000609; US 2000233345 P 20000918; US 2000709035 A 20001108; US 2001758403 A 20010110; US 2001766168 A 20010119; US 2001836940 A 20010417; US 2001326516 P 20011002

Patent Details:

Patent No	Kind	Lan	Pg	Main	IPC	Filing Notes
US 20030097129	A1	129	A61B-018/14			CIP of application US 9810382
						CIP of application US 98197013
						Provisional application US 2000210567
						Provisional application US 2000233345
						CIP of application US 2000709035
						CIP of application US 2001758403
						CIP of application US 2001766168
						CIP of application US 2001836940
						Provisional application US 2001326516
						CIP of patent US 6190381
						CIP of patent US 6296638

...Inventor: ORMSBY T C

International Patent Class (Main): A61B-018/14

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8/3,K/9 (Item 9 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015431445 \*\*Image available\*\*

WPI Acc No: 2003-493587/200346  
XRPX Acc No: N03-392084

**Shapeable curvilinear radio frequency antenna apparatus for ablating biological tissue has flexible catheter body, inner and outer coaxially aligned conductors and flexible shapeable curvilinear antenna**

Patent Assignee: MEDWAVES INC (MEDW-N)

Inventor: LAW M ; LEUNG G L ; ORMSBY T C

Number of Countries: 102 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat. No	Kind	Date	Week
WO 200347448	A1	20030612	WO 2002US37886	A	20021127	200346 B
US 20030114844	A1	20030619	US 2001334199	P	20011129	200355
			US 2002306757	A	20021127	
AU 2002365882	A1	20030617	AU 2002365882	A	20021127	200419

Priority Applications (No Type Date): US 2001334199 P 20011129; US 2002306757 A 20021127

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200347448	A1	E	48	A61B-018/18	
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Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SC SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU ZA ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW

US 20030114844	A1			A61B-018/18	Provisional application US 2001334199
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AU 2002365882	A1			A61B-018/18	Based on patent WO 200347448
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Inventor: LAW M ...

... LEUNG G L ...

... ORMSBY T C

International Patent Class (Main): A61B-018/18

International Patent Class (Additional): A61B-005/04 ...

... A61B-005/044

8/3,K/10 (Item 10 from file: 350)

DIALOG(R)File 350:Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

015360247 \*\*Image available\*\*

WPI Acc No: 2003-421185/200339

Related WPI Acc No.: 1996-476776; 1997-051698; 1997-297829; 1997-297832;

1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;  
1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-113443; 2002-121081; 2002-147711;  
2002-163510; 2002-170989; 2002-206288; 2002-214577; 2002-370567;  
2002-636083; 2002-691219; 2003-015692; 2003-028464; 2003-254801;  
2003-330499; 2003-361993; 2003-417299; 2003-419759; 2003-567867;  
2003-576879; 2003-707520; 2003-755934; 2003-778898; 2003-801399;  
2003-895627; 2003-898307; 2003-902058; 2004-167062; 2004-167544;

See claims 38+  
in US  
version

29 Nov  
2001

Provisional  
File  
Date

2004-224783; 2004-238519; 2004-327350  
XRAM Acc No: C03-110841  
XRPX Acc No: N03-336494

**Electrosurgical probe for removing target tissue, e.g. sinus tissue, at surgical site, includes active electrode assembly having flow protector(s) protruding from treatment surface, and active electrode screen**

Patent Assignee: ARTHROCARE CORP (ARTH-N)  
Inventor: DAHLA R H; DAVISON T S; ORMSBY T C ; WOLOSZKO J  
Number of Countries: 100 Number of Patents: 002  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200328542	A2	20030410	WO 2002US31640	A	20021002	200339 B
EP 1437977	A2	20040721	EP 2002768969	A	20021002	200447
			WO 2002US31640	A	20021002	

Priority Applications (No Type Date): US 2001326516 P 20011002

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200328542	A2	E	221	A61B-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG UZ VN YU ZA  
ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB  
GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW

EP 1437977 A2 E A61B-018/14 Based on patent WO 200328542

Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR (

...Inventor: ORMSBY T C

International Patent Class (Main): A61B-000/00 ...

... A61B-018/14

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8/3,K/11 (Item 11 from file: 350)

DIALOG(R)File 350:Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

015357013 \*\*Image available\*\*

WPI Acc No: 2003-417951/200339

Related WPI Acc No: 2000-365053; 2002-391856

XRPX Acc No: N03-333352

**Ablation instrument installing apparatus has support face which forms hermetic seal against biological tissue during operation of vacuum source to retain ablation instrument**

Patent Assignee: BERUBE D (BERU-I); ERB L (ERBL-I); MATHENY R (MATH-I);  
ORMSBY T C (ORMS-I); WOODARD R E (WOOD-I)

Inventor: BERUBE D; ERB L; MATHENY R; ORMSBY T C ; WOODARD R E

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030036754	A1	20030220	US 98178066	A	19981023	200339 B
			US 99398723	A	19990920	
			US 2002115115	A	20020401	

Priority Applications (No Type Date): US 99398723 A 19990920; US 98178066 A  
19981023; US 2002115115 A 20020401

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes  
US 20030036754 A1 22 A61B-018/18 CIP of application US 98178066  
Cont of application US 99398723  
CIP of patent US 6245062  
Cont of patent US 6364876

...Inventor: ORMSBY T C

Abstract (Basic):

... element of microwave ablation instrument proximate to targeted  
region of biological tissue, for treatment of atrial arrhythmia .

International Patent Class (Main): A61B-018/18

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8/3,K/12 (Item 12 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015301059 \*\*Image available\*\*

WPI Acc No: 2003-361993/200334

Related WPI Acc No: 1996-476776; 1997-051698; 1997-297829; 1997-297832;  
1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;  
1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-113443; 2002-121081; 2002-147711;  
2002-163510; 2002-206288; 2002-214577; 2002-370567; 2002-636083;  
2002-691219; 2003-015692; 2003-028464; 2003-254801; 2003-330499;  
2003-417299; 2003-419759; 2003-421185; 2003-567867; 2003-576879;  
2003-707520; 2003-755934; 2003-778898; 2003-801399; 2003-895627;  
2003-898307; 2003-902058; 2004-167062; 2004-167544; 2004-224783;  
2004-238519; 2004-327350

XRAM Acc No: C03-095521

XRPX Acc No: N03-289051

Fluid delivery unit for electrosurgical instrument, comprises tube with  
proximal portion that connects to fluid source, and distal portion with  
second arm that terminates near closed tube terminus

Patent Assignee: ARTHROCARE CORP (ARTH-N)

Inventor: ORMSBY T C ; TSUJI C; WOLOSZKO J

Number of Countries: 101 Number of Patents: 004

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20030009164	A1	20030109	US 95485219	A	19950607	200334 B
			US 97990374	A	19971215	
			US 9841934	A	19980313	
			US 2000182751	P	20000216	
			US 2001839427	A	20010420	
			US 2001304297	P	20010709	
			US 200257412	A	20020125	
WO 200305882	A2	20030123	WO 2002US21582	A	20020709	200334
EP 1411847	A2	20040428	EP 2002765814	A	20020709	200429
			WO 2002US21582	A	20020709	
AU 2002329212	A1	20030129	AU 2002329212	A	20020709	200452

Priority Applications (No Type Date): US 200257412 A 20020125; US 95485219  
A 19950607; US 97990374 A 19971215; US 9841934 A 19980313; US 2000182751  
P 20000216; US 2001839427 A 20010420; US 2001304297 P 20010709

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

US 20030009164 A1 104 A61B-018/14 CIP of application US 95485219  
CIP of application US 97990374  
CIP of application US 9841934  
Provisional application US 2000182751  
CIP of application US 2001839427  
Provisional application US 2001304297  
CIP of patent US 5697281  
CIP of patent US 6109268  
CIP of patent US 6391025

WO 200305882 A2 E A61B-000/00  
Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG UZ VN YU ZA  
ZM ZW  
Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB  
GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW  
EP 1411847 A2 E A61B-018/14 Based on patent WO 200305882  
Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR  
AU 2002329212 A1 A61B-018/14 Based on patent WO 200305882  
Inventor: ORMSBY T C ...  
International Patent Class (Main): A61B-000/00 ...

... A61B-018/14

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8/3,K/13 (Item 13 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014571152 \*\*Image available\*\*  
WPI Acc No: 2002-391856/200242  
Related WPI Acc No: 2000-365053; 2003-417951  
XRPX Acc No: N02-307022

Holding apparatus used in ablation instrument system, forms hermetic seal  
between support base and biological tissue provided near antenna of  
ablation instrument, during operation of vacuum source

Patent Assignee: AFX INC (AFXA-N)  
Inventor: BERUBE D; ERB L; MATHENY R; ORMSBY T C ; WOODARD R E  
Number of Countries: 001 Number of Patents: 001  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6364876	B1	20020402	US 98178066	A	19981023	200242 B
			US 99398723	A	19990920	

Priority Applications (No Type Date): US 99398723 A 19990920; US 98178066 A  
19981023

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 6364876	B1	21	A61B-018/18	CIP of application US 98178066

...Inventor: ORMSBY T C  
International Patent Class (Main): A61B-018/18

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8/3,K/14 (Item 14 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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014292741 \*\*Image available\*\*

WPI Acc No: 2002-113443/200215

Related WPI Acc No: 1996-476776; 1997-051698; 1997-297829; 1997-297832;  
1998-120425; 1998-120493; 1998-530718; 1999-059988; 1999-130298;  
1999-179878; 1999-214453; 1999-277173; 1999-312540; 1999-312547;  
1999-385169; 1999-395076; 1999-518494; 1999-580571; 2000-062120;  
2000-195426; 2000-204827; 2000-237402; 2000-255603; 2000-422843;  
2000-531792; 2000-542909; 2000-587596; 2001-049631; 2001-069745;  
2001-070821; 2001-225913; 2001-343206; 2001-424601; 2001-522540;  
2001-646987; 2002-082230; 2002-121081; 2002-147711; 2002-163510;  
2002-170989; 2002-206288; 2002-214577; 2002-370567; 2002-636083;  
2002-691219; 2003-015692; 2003-028464; 2003-246251; 2003-254801;  
2003-330499; 2003-361993; 2003-417299; 2003-419759; 2003-421185;  
2003-567867; 2003-576879; 2003-707520; 2003-755934; 2003-778898;  
2003-801399; 2003-895627; 2003-898307; 2003-902058; 2004-167062;  
2004-167544; 2004-224783; 2004-238519; 2004-327350

XRPX Acc No: N02-084519

**Electrosurgical suction apparatus for tissue treatment, has active electrodes which extends distally in two different directions, respectively**

Patent Assignee: ARTHROCARE CORP (ARTH-N)

Inventor: DAVISON T S; MASTERSON S P; ORMSBY T C ; WILLINK C L; WOLOSZKO J

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20010051802	A1	20011213	US 2000233345	P	20000918	200215 B
			US 2001766168	A	20010119	

Priority Applications (No Type Date): US 2000233345 P 20000918; US 2001766168 A 20010119

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20010051802	A1	110	A61B-018/14	Provisional application	US 2000233345

...Inventor: ORMSBY T C  
International Patent Class (Main): A61B-018/14

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8/3,K/15 (Item 15 from file: 350)

DIALOG(R)File 350:Derwent WPIX

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013979454 \*\*Image available\*\*

WPI Acc No: 2001-463668/200150

Related WPI Acc No: 2000-237390

XRPX Acc No: N01-343739

**Navigating and advancing method for deploying guidewire through complex lesion occluding blood vessels, involves using ultrasound transducer for ultrasound imaging of occlusion and blood vessel**

Patent Assignee: FOX HOLLOW TECHNOLOGIES INC (FOXH-N)

Inventor: FRISBIE J S; IMRAN M A; KATOH O; MCGILL S A; ORMSBY T C ; SYKES C M; VAN BLADEL K H

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6241744	B1	20010605	US 98134744	A	19980814	200150 B
			US 98216629	A	19981216	

Priority Applications (No Type Date): US 98216629 A 19981216; US 98134744 A 19980814

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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US 6241744 B1 20 A61B-017/22 CIP of application US 98134744  
...Inventor: ORMSBY T C  
International Patent Class (Main): A61B-017/22

8/3,K/16 (Item 16 from file: 350)

DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

013360613 \*\*Image available\*\*  
WPI Acc No: 2000-532552/200048  
Related WPI Acc No: 2004-118192; 2004-497634  
XRPX Acc No: N00-393932

Electrical hollow coaxial cable for use in medical field, has outer  
conductor made of electrically conductive braided material or thin film  
material, over inner conductor provided with axial lumen

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I);  
MEDWAVES INC (MEDW-N)

Inventor: LAW M ; LEUNG G L ; ORMSBY T C  
Number of Countries: 085 Number of Patents: 008  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200035363	A1	20000622	WO 99US29148	A	19991208	200048 B
AU 200031152	A	20000703	AU 200031152	A	19991208	200051
EP 1054639	A1	20001129	EP 99965180	A	19991208	200063
			WO 99US29148	A	19991208	
US 6190382	B1	20010220	US 98211188	A	19981214	200112
CN 1290148	A	20010404	CN 99802890	A	19991208	200140
KR 2001040944	A	20010515	KR 2000708865	A	20000812	200167
JP 2002532132	W	20021002	WO 99US29148	A	19991208	200279
			JP 2000587685	A	19991208	
TW 495354	A	20020721	TW 2000109908	A	20000523	200332 N

Priority Applications (No Type Date): US 98211188 A 19981214; TW 2000109908  
A 20000523

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200035363	A1	E	37	A61B-018/04	
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Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN  
CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ  
LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK  
SL TJ TM TR TT UA UG US UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU  
MC NL PT SE

AU 200031152	A				Based on patent WO 200035363
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EP 1054639	A1	E			Based on patent WO 200035363
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Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI  
LU MC NL PT SE

JP 2002532132	W		37	A61B-018/14	Based on patent WO 200035363
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TW 495354	A			A61B-017/36	
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Inventor: LAW M ...

... LEUNG G L ...

... ORMSBY T C

Abstract (Basic):

... tissues in body vessels e.g. arteries or veins of patients, for  
the treatment of cardiac arrhythmias .

International Patent Class (Main): A61B-017/36 ...



... A61B-018/04 ...

... A61B-018/14

International Patent Class (Additional): A61B-017/00 ...

... A61B-018/18

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8/3,K/17 (Item 17 from file: 350)

DIALOG(R)File 350:Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

013293250 \*\*Image available\*\*

WPI Acc No: 2000-465185/200040

XRPX Acc No: N00-347254

Guide wire used in treatment of stenoses in arterial vessels, includes flexible tube having uniform diameter with sidewise focusing transducer at distal extremity that rotates as tube is rotated

Patent Assignee: FOX HOLLOW TECHNOLOGIES INC (FOXH-N)

Inventor: IMRAN M A; ORMSBY T C ; VAN BLADEL K H

Number of Countries: 088 Number of Patents: 002

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200035349	A1	20000622	WO 99US30126	A	19991216	200040 B
AU 200019402	A	20000703	AU 200019402	A	19991216	200046

Priority Applications (No Type Date): US 98216628 A 19981216

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200035349	A1	E	21	A61B-008/00	
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Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW

AU 200019402	A	A61B-008/00	Based on patent WO 200035349
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...Inventor: ORMSBY T C

International Patent Class (Main): A61B-008/00

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8/3,K/18 (Item 18 from file: 350)

DIALOG(R)File 350:Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

013193180 \*\*Image available\*\*

WPI Acc No: 2000-365053/200031

Related WPI Acc No: 2002-391856; 2003-417951

XRAM Acc No: C00-110148

XRPX Acc No: N00-273222

Directional reflector shield assembly for a microwave ablation instrument having an antenna coupled to a transmission line has a cradle device disposed on the antenna to shield the surrounding area from the electric field

Patent Assignee: FIDUS MEDICAL TECHNOLOGY CORP (FIDU-N); AFX INC (AFXA-N);

BERUBE D (BERU-I); ORMSBY T C (ORMS-I); WOODARD R E (WOOD-I)

Inventor: BERUBE D; ORMSBY T C ; WOODARD R E

Number of Countries: 020 Number of Patents: 007

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200024463	A2	20000504	WO 99US24047	A	19991022	200031 B
US 6245062	B1	20010612	US 98178066	A	19981023	200135
EP 1123135	A2	20010816	EP 99954926	A	19991022	200147
			WO 99US24047	A	19991022	
US 6312427	B1	20011106	US 98178066	A	19981023	200170
			US 2000496477	A	20000202	
US 6383182	B1	20020507	US 98178066	A	19981023	200235
			US 2000651560	A	20000830	
US 20020128642	A1	20020912	US 98178066	A	19981023	200262
			US 2000651560	A	20000830	
			US 2002140551	A	20020506	
US 20020193786	A1	20021219	US 98178066	A	19981023	200303
			US 2000651560	A	20000830	
			US 2002123849	A	20020415	

Priority Applications (No Type Date): US 98178066 A 19981023; US 2000496477 A 20000202; US 2000651560 A 20000830; US 2002140551 A 20020506; US 2002123849 A 20020415

#### Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
WO 200024463	A2 E	36	A61N-005/00	
Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE				
US 6245062	B1		A61B-018/04	
EP 1123135	A2 E		A61N-005/00	Based on patent WO 200024463
Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE				
US 6312427	B1		A61B-018/04	Div ex application US 98178066
US 6383182	B1		A61B-018/18	Cont of application US 98178066
US 20020128642	A1		A61B-018/18	Cont of application US 98178066 Cont of application US 2000651560 Cont of patent US 6245062 Cont of patent US 6383182
US 20020193786	A1		A61B-018/18	Cont of application US 98178066 Cont of application US 2000651560 Cont of patent US 6245062 Cont of patent US 6383182

...Inventor: ORMSBY T C

International Patent Class (Main): A61B-018/04 ...

... A61B-018/18

8/3,K/19 (Item 19 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

013065518 \*\*Image available\*\*  
WPI Acc No: 2000-237390/200020  
Related WPI Acc No: 2001-463668  
XRPX Acc No: N00-178080

Device to deploy guide wire across complex lesion in vessel; has long flexible catheter with several separate spaced apart extended lumens  
Patent Assignee: REFLOW INC (REFL-N)  
Inventor: FRISBIE J S; IMRAN M A; KATOH O; MCGILL S A; ORMSBY T C ; SYKES C M; VAN BLADEL K H  
Number of Countries: 085 Number of Patents: 002  
Patent Family:  
Patent No Kind Date Applicat No Kind Date Week

WO 200009020 A1 20000224 WO 99US18526 A 19990813 200020 B  
AU 9955626 A 20000306 AU 9955626 A 19990813 200030

Priority Applications (No Type Date): US 98134744 A 19980814

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200009020 A1 E 67 A61B-017/22

Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN  
CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ  
LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK  
SL TJ TM TR TT UA UG UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR  
IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW

AU 9955626 A A61B-017/22 Based on patent WO 200009020

...Inventor: ORMSBY T C

International Patent Class (Main): A61B-017/22

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Set	Items	Description
S1	73	AU=(FELD G? OR FELD, G? OR ORMSBY T? OR ORMSBY, T? OR LAW - M? OR LAW, M? OR LAW MF OR LAW, MF OR LEUNG G? OR LEUNG, G?)
S2	28	GREG?(2N)FELD OR (THEODORE OR TED) (2N)ORMSBY OR MING?(2N)L- AW OR GEORGE(2N)LEUNG
S3	11363	(FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLU- TTER?) AND (ATRIU? OR ATRIA? OR CARDI?)
S4	55396	IC=A61B?
S5	9	S1:S2 AND S3
S6	17	S1:S2 AND S4
S7	21	S5:S6
S8	21	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 348:EUROPEAN PATENTS 1978-2004/Sep W01

(c) 2004 European Patent Office

File 349:PCT FULLTEXT 1979-2002/UB=20040909,UT=20040902

(c) 2004 WIPO/Univentio

8/3,AU/1 (Item 1 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01615625

**RADIO-FREQUENCY-BASED CATHETER SYSTEM WITH IMPROVED DEFLECTION  
AND STEERING MECHANISMS**

**SYSTEME DE CATHETER A RADIOFREQUENCE AVEC MECANISMES DE DEVIATION ET DE  
GUIDAGE AMELIORES**

PATENT ASSIGNEE:

Medwaves, Inc., (4458290), 6885 Flanders Drive, Suite B, San Diego, CA  
92121-2933, (US), (Applicant designated States: all)

INVENTOR:

ORMSBY , Theodore , C., 2357 Dubois Street, Milpitas, CA 95035, (US)

LAW , Ming -Fan, 12344 Picrus Street, San Diego, CA 92129, (US)

LEUNG , George , L., 12516 Cloudesly Drive, San Diego, CA 92128, (US)

PATENT (CC, No, Kind, Date):

WO 2003047448 030612

APPLICATION (CC, No, Date): EP 2002804448 021127; WO 2002US37886 021127

PRIORITY (CC, No, Date): US 334199 P 011129

DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR;  
IE; IT; LI; LU; MC; NL; PT

EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

INTERNATIONAL PATENT CLASS: A61B-018/18 ; A61B-005/04 ; H01Q-001/36

LANGUAGE (Publication,Procedural,Application): English; English; English

8/3,AU/2 (Item 2 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

01017867

**RADIO-FREQUENCY-BASED CATHETER SYSTEM WITH IMPROVED DEFLECTION AND STEERING  
MECHANISMS**

**SYSTEME DE CATHETER A RADIOFREQUENCE AVEC MECANISMES DE DEVIATION ET DE  
GUIDAGE AMELIORES**

Patent Applicant/Assignee:

MEDWAVES INC, 6885 Flanders Drive, Suite B, San Diego, CA 92121-2933, US,  
US (Residence), US (Nationality)

Inventor(s):

ORMSBY Theodore C , 2357 Dubois Street, Milpitas, CA 95035, US,

LAW Ming-Fan , 12344 Picrus Street, San Diego, CA 92129, US,

LEUNG George L , 12516 Cloudesly Drive, San Diego, CA 92128, US

Legal Representative:

BEUERLE Stephen C (agent), Procopio, Cory, Hargreaves & Savitch, LLP, 530  
B Street, Suite 2100, San Diego, CA 92101-4469, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200347448 A1 20030612 (WO 0347448)

Application: WO 2002US37886 20021127 (PCT/WO US0237886)

Priority Application: US 2001334199 20011129

Designated States:

(Protection type is "patent" unless otherwise stated - for applications  
prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ  
EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR  
LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SC SD SE SG  
SI SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU ZA ZM ZW

(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR

(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW

(EA) AM AZ BY KG KZ MD RU TJ TM  
Publication Language: English  
Filing Language: English  
Fulltext Word Count: 10881

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8/3,AU/3 (Item 3 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01588534

APPARATUS AND METHODS FOR ELECTROSURGICAL REMOVAL AND DIGESTION OF TISSUE  
GERAT UND VERFAHREN FUR DIE ELEKTROCHIRURGISCHE ENTFERNUNG UND DEN  
AUFSCHLUSS VON GEWEBE

APPAREIL ET PROCEDES D'ABLATION ET DE DIGESTION ELECTROCHIRURGICALES DE  
TISSU

PATENT ASSIGNEE:

ArthroCare Corporation, (2064792), 680 Vaqueros Avenue, Sunnyvale,  
California 94085-3523, (US), (Applicant designated States: all)

INVENTOR:

DAVISON, Terry, S., 69 A Mirabel Avenue, San Francisco, CA 94110, (US)

ORMSBY, Theodore, C., 2357 Dubois Street, Milpitas, CA 95035, (US)

WOLOSZKO, Jean, 1694 Columbia Drive, Mountain View, CA 94040, (US)

DAHLA, Robert, H., 1227 Valerian Court, 3, Sunnyvale, CA 94086, (US)

LEGAL REPRESENTATIVE:

Kazi, Ilya et al (86111), Mathys & Squire, 100 Gray's Inn Road, London  
WC1X 8AL, (GB)

PATENT (CC, No, Kind, Date): EP 1437977 A2 040721 (Basic)  
WO 2003028542 030410

APPLICATION (CC, No, Date): EP 2002768969 021002; WO 2002US31640 021002

PRIORITY (CC, No, Date): US 326516 P 011002

DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR;  
IE; IT; LI; LU; MC; NL; PT; SE; SK; TR

EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

INTERNATIONAL PATENT CLASS: A61B-018/14

NOTE:

No A-document published by EPO

LANGUAGE (Publication,Procedural,Application): English; English; English

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8/3,AU/4 (Item 4 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

01000589

APPARATUS AND METHODS FOR ELECTROSURGICAL REMOVAL AND DIGESTION OF TISSUE

APPAREIL ET PROCEDES D'ABLATION ET DE DIGESTION ELECTROCHIRURGICALES DE  
TISSU

Patent Applicant/Assignee:

ARTHROCARE CORPORATION, 680 Vaqueros Avenue, Sunnyvale, CA 94085, US, US  
(Residence), US (Nationality)

Inventor(s):

DAVISON Terry S, 69 A Mirabel Avenue, San Francisco, CA 94110, US,

ORMSBY Theodore C, 2357 Dubois Street, Milpitas, CA 95035, US,

WOLOSZKO Jean, 1694 Columbia Drive, Mountain View, CA 94040, US,

DAHLA Robert H, 1227 Valerian Court,#3, Sunnyvale, CA 94086, US

Legal Representative:

BAGADE Sanjay S (agent), ArthroCare Corporation, 680 Vaqueros Avenue,  
Sunnyvale, CA 94085, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200328542 A2-A3 20030410 (WO 0328542)  
Application: WO 2002US31640 20021002 (PCT/WO US0231640)  
Priority Application: US 2001326516 20011002

**Designated States:**

(Protection type is "patent" unless otherwise stated - for applications prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ  
EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR  
LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI  
SK SL TJ TM TN TR TT TZ UA UG UZ VN YU ZA ZM ZW  
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR  
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG  
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW  
(EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English

Filing Language: English

Fulltext Word Count: 53814

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**8/3,AU/5 (Item 5 from file: 348)**

DIALOG(R)File 348:EUROPEAN PATENTS

(c) 2004 European Patent Office. All rts. reserv.

01557127

**ARTICULATED ELECTROSURGICAL PROBE**  
**GELENKIGE ELEKTROCHIRURGISCHE SONDE**  
**SONDE ELECTROCHIRURGICALE ARTICULEE**  
**PATENT ASSIGNEE:**

ArthroCare Corporation, (2064792), 680 Vaqueros Avenue, Sunnyvale,  
California 94085-3523, (US), (Applicant designated States: all)

**INVENTOR:**

WOLOSZKO, Jean, 1694 Columbia Drive, Mountain View, CA 94040, (US)  
TSUJI, Craig, 3419 Cadillac Road, San Jose, CA 95117, (US)

**ORMSBY, Theodore**, C., 2357 Dubois Street, Milpitas, CA 95035, (US)

**LEGAL REPRESENTATIVE:**

Kazi, Ilya et al (86111), Mathys & Squire, 100 Gray's Inn Road, London  
WC1X 8AL, (GB)

PATENT (CC, No, Kind, Date): EP 1411847 A2 040428 (Basic)  
WO 2003005882 030123

APPLICATION (CC, No, Date): EP 2002765814 020709; WO 2002US21582 020709

PRIORITY (CC, No, Date): US 304297 P 010709; US 57412 020125

DESIGNATED STATES: AT; BE; BG; CH; CY; CZ; DE; DK; EE; ES; FI; FR; GB; GR;  
IE; IT; LI; LU; MC; NL; PT; SE; SK; TR

EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

INTERNATIONAL PATENT CLASS: **A61B-018/14**

**NOTE:**

No A-document published by EPO

LANGUAGE (Publication,Procedural,Application): English; English; English

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**8/3,AU/6 (Item 6 from file: 349)**

DIALOG(R)File 349:PCT FULLTEXT

(c) 2004 WIPO/Univentio. All rts. reserv.

00977651

**ARTICULATED ELECTROSURGICAL PROBE**  
**SONDE ELECTROCHIRURGICALE ARTICULEE**  
**Patent Applicant/Assignee:**

ARTHROCARE CORPORATION, 680 Vaqueros Avenue, Sunnyvale, CA 94085, US, US  
(Residence), US (Nationality)

Inventor(s):

WOLOSZKO Jean, 1694 Columbia Drive, Mountain View, CA 94040, US,  
TSUJI Craig, 3419 Cadillac Road, San Jose, CA 95117, US,  
ORMSBY Theodore C , 2357 Dubois Street, Milpitas, CA 95035, US

Legal Representative:

BAGADE Sanjay S (agent), ArthroCare Corporation, 680 Vaqueros Avenue,  
Sunnyvale, CA 94085, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200305882 A2-A3 20030123 (WO 0305882)  
Application: WO 2002US21582 20020709 (PCT/WO US0221582)  
Priority Application: US 2001304297 20010709; US 200257412 20020125

Designated States:

(Protection type is "patent" unless otherwise stated - for applications  
prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ  
EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR  
LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI  
SK SL TJ TM TN TR TT TZ UA UG UZ VN YU ZA ZM ZW  
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR  
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG  
(AP) GH GM KE LS MW SD SL SZ TZ UG ZM ZW  
(EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English

Filing Language: English

Fulltext Word Count: 40409

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8/3,AU/7 (Item 7 from file: 348)

DIALOG(R)File 348:EUROPEAN PATENTS

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01415142

**APPARATUS FOR TREATMENT OF SPINAL DISORDERS**

**GERAT ZUR BEHANDLUNG VON SPINALEN ABWEICHUNGEN**

**APPAREILS POUR LE TRAITEMENT DES TROUBLES DE LA COLONNE VERTEBRALE**

**PATENT ASSIGNEE:**

ArthroCare Corporation, (2064791), 680 Vaqueros Avenue, Sunnyvale,  
California 940865-3523, (US), (Applicant designated States: all)

**INVENTOR:**

WOLOSZKO, Jean, 1694 Columbia Drive, Mountain View, CA 94040, (US)  
SHARPS, Lewis, 911 Lafayette Road, Bryn Mawr, PA 19010, (US)  
HOVDA, David, C., 1900 Miramonte Avenue, Mountain View, CA 94040, (US)  
ORMSBY , Theodore , C., 2357 Dubois Street, Milpitas, CA 95035, (US)  
QUACKENBUSH, John, J., 2600 Knightsbridge Lane, Santa Clara, CA 95051,  
(US)

MARTINI, Brian, 25 Harrison Way, Menlo Park, CA 94025, (US)  
THAPLIYAL, Hira, V., 1192 Volti Lane, Los Altos, CA 94024, (US)  
EGGERS, Philip, E., 4140 Tuller Road, 104 Dublin, Ohio 43017, (US)

**LEGAL REPRESENTATIVE:**

Kazi, Ilya et al (86111), Mathys & Squire, 100 Gray's Inn Road, London  
WC1X 8AL, (GB)

PATENT (CC, No, Kind, Date): EP 1309282 A1 030514 (Basic)

WO 2002011635 020214

APPLICATION (CC, No, Date): EP 2001935554 010515; WO 2001US15728 010515

PRIORITY (CC, No, Date): US 224107 P 000809; US 676194 000928; US 679394  
001003

DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;  
LU; MC; NL; PT; SE; TR

EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

INTERNATIONAL PATENT CLASS: A61B-018/14

NOTE:



No A-document published by EPO  
LANGUAGE (Publication,Procedural,Application): English; English; English

8/3,AU/8 (Item 8 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

00877959

**APPARATUS FOR TREATMENT OF SPINAL DISORDERS**

**APPAREILS POUR LE TRAITEMENT DES TROUBLES DE LA COLONNE VERTEBRALE**

Patent Applicant/Assignee:

ARTHROCARE CORPORATION, 595 N. Pastoria Avenue, Sunnyvale, CA 94085-2936,  
US, US (Residence), US (Nationality)

Inventor(s):

WOLOSZKO Jean, 1694 Columbia Drive, Mountain View, CA 94040, US,  
SHARPS Lewis, 911 Lafayette Road, Bryn Mawr, PA 19010, US,  
HOVDA David C, 1900 Miramonte Avenue, Mountain View, CA 94040, US,  
ORMSBY Theodore C , 2357 Dubois Street, Milpitas, CA 95035, US,  
QUACKENBUSH John J, 2441 Austin Place, Santa Clara, CA 95050, US,  
MARTINI Brian, 25 Harrison Way, Menlo Park, CA 94025, US,  
THAPLIYAL Hira V, 1192 Volti Lane, Los Altos, CA 94024, US,  
EGGERS Philip E, 5366 Reserve Drive, Dublin, OH 43017, US

Legal Representative:

RAFFLE John T (agent), ArthroCare Corporation, 595 N. Pastoria Avenue,  
Sunnyvale, CA 94086-2936, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200211635 A1 20020214 (WO 0211635)

Application: WO 2001US15728 20010515 (PCT/WO US0115728)

Priority Application: US 2000224107 20000809; US 2000676194 20000928; US  
2000679394 20001003

Designated States:

(Protection type is "patent" unless otherwise stated - for applications  
prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE  
ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT  
LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM  
TR TT TZ UA UG UZ VN YU ZA ZW

(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR

(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG

(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW

(EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English

Filing Language: English

Fulltext Word Count: 38679

8/3,AU/9 (Item 9 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01392071

**ELECTROSURGICAL APPARATUS AND METHODS FOR ABLATING TISSUE**

**ELEKTROCHIRURGISCHES GERAT UND VERFAHREN ZUR GEWEBEABLATION**

**APPAREIL ELECTROCHIRURGICAL ET TECHNIQUE D'ABLATION DE TISSU**

PATENT ASSIGNEE:

ARTHROCARE CORPORATION, (2064795), 595 North Pastoria Avenue, Sunnyvale,  
California 94085-2936, (US), (Applicant designated States: all)

INVENTOR:

WOLOSZKO, Jean, 1694 Columbia Drive, Mountain View, CA 94040, (US)

DAVISON, Terry, S., 69A Mirabel Avenue, San Francisco, CA 94110, (US)

ORMSBY , Theodore , C., 2357 Dubois Street, Milpitas, CA 95035, (US)  
WILLINK, Christopher, L., 126 Ada Avenue, Mountain View, CA 94043, (US)  
MASTERSON, Steven, P., 1901 Mariposa, San Francisco, CA 94107, (US)  
HOVDA, David, C., 1900 Miramonte Avenue, Mountain View, CA 94040, (US)  
THAPLIYAL, Hira, V., 1192 Volti Lane, Los Altos, CA 94024, (US)  
EGGERS, Philip, E., 5366 Reserve Drive, Dublin, OH 43017, (US)  
LEGAL REPRESENTATIVE:  
Kazi, Ilya et al (86111), Mathys & Squire, 100 Gray's Inn Road, London  
WC1X 8AL, (GB)  
PATENT (CC, No, Kind, Date): EP 1289438 A1 030312 (Basic)  
WO 2001095819 011220  
APPLICATION (CC, No, Date): EP 2001935650 010516; WO 2001US16006 010516  
PRIORITY (CC, No, Date): US 210567 P 000609; US 233345 P 000918; US 709035  
001108; US 758403 010110; US 766168 010119; US 836940 010417  
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;  
LU; MC; NL; PT; SE; TR  
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI  
INTERNATIONAL PATENT CLASS: A61B-018/14  
NOTE:  
No A-document published by EPO  
LANGUAGE (Publication,Procedural,Application): English; English; English

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8/3,AU/10 (Item 10 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

00862658

**ELECTROSURGICAL APPARATUS AND METHODS FOR ABLATING TISSUE**  
**APPAREIL ELECTROCHIRURGICAL ET TECHNIQUE D'ABLATION DE TISSU**

Patent Applicant/Assignee:

ARTHROCARE CORPORATION, 595 N. Pastoria Avenue, Sunnyvale, CA 94085, US,  
US (Residence), US (Nationality)

Inventor(s):

WOLOSZKO Jean, 1694 Columbia Drive, Mountain View, CA 94040, US,  
DAVISON Terry S, 69A Mirabel Avenue, San Francisco, CA 94110, US,  
ORMSBY Theodore C , 2357 Dubois Street, Milpitas, CA 95035, US,  
WILLINK Christopher L, 126 Ada Avenue, Mountain View, CA 94043, US,  
MASTERSON Steven P, 1901 Mariposa, San Francisco, CA 94107, US,  
HOVDA David C, 1900 Miramonte Avenue, Mountain View, CA 94040, US,  
THAPLIYAL Hira V, 1192 Volti Lane, Los Altos, CA 94024, US,  
EGGERS Philip E, 5366 Reserve Drive, Dublin, OH 43017, US

Legal Representative:

RAFFLE John T (agent), ArthroCare Corporation, 595 N. Pastoria Avenue,  
Sunnyvale, CA 94085, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200195819 A1 20011220 (WO 0195819)

Application: WO 2001US16006 20010516 (PCT/WO US0116006)

Priority Application: US 2000210567 20000609; US 2000233345 20000918; US  
2000709035 20001108; US 2001758403 20010110; US 2001766168 20010119; US  
2001836940 20010417

Designated States:

(Protection type is "patent" unless otherwise stated - for applications  
prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE  
ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT  
LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM  
TR TT TZ UA UG UZ VN YU ZA ZW

(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR

(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG

(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW

(EA) AM AZ BY KG KZ MD RU TJ TM  
Publication Language: English  
Filing Language: English  
Fulltext Word Count: 50555

8/3,AU/11 (Item 11 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01180800

RADIO-FREQUENCY BASED CATHETER SYSTEM AND HOLLOW CO-AXIAL CABLE FOR  
ABLATION OF BODY TISSUES

HOCHFREQUENZKATHETER UND KOAXIALES HOHLKABEL ZUR ABLATION UND KORPERGEWEBE  
CATHETER DIFFUSEUR D'ONDES RF ET CABLE COAXIAL CREUX SERVANT A L'ABLATION  
DE TISSUS CORPORELS

PATENT ASSIGNEE:

Ormsby , Theodore C., (3053010), 2357 Dubois Street, Milpitas, CA  
95035, (US), (Applicant designated States: all)  
Leung , George L., (3053030), 12516 Cloudesly Drive, San Diego, CA  
92128, (US), (Applicant designated States: all)  
Law , Ming -Fan, (3053040), 12344 Picrus Street, San Diego, CA 92129,  
(US), (Applicant designated States: all)

INVENTOR:

Ormsby , Theodore C., 2357 Dubois Street, Milpitas, CA 95035, (US)  
Leung , George L., 12516 Cloudesly Drive, San Diego, CA 92128, (US)  
Law , Ming -Fan, 12344 Picrus Street, San Diego, CA 92129, (US)

LEGAL REPRESENTATIVE:

Copp, David Christopher et al (29633), Dummett Copp, 25 The Square,  
Martlesham Heath, Ipswich, Suffolk IP5 3SL, (GB)

PATENT (CC, No, Kind, Date): EP 1054639 A1 001129 (Basic)  
WO 0035363 000622

= (US) 6190382

APPLICATION (CC, No, Date): EP 99965180 991208; WO 99US29148 991208

PRIORITY (CC, No, Date): US 211188 981214

DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;  
LU; MC; NL; PT; SE

INTERNATIONAL PATENT CLASS: A61B-018/04

NOTE:

No A-document published by EPO

LANGUAGE (Publication,Procedural,Application): English; English; English

8/3,AU/12 (Item 12 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

00571990

RADIO-FREQUENCY BASED CATHETER SYSTEM AND HOLLOW CO-AXIAL CABLE FOR  
ABLATION OF BODY TISSUES

CATHETER DIFFUSEUR D'ONDES RF ET CABLE COAXIAL CREUX SERVANT A L'ABLATION  
DE TISSUS CORPORELS

Patent Applicant/Assignee:

ORMSBY Theodore C,  
LEUNG George L,  
LAW Ming.-Fan

Inventor(s):

ORMSBY Theodore C ,  
LEUNG George L ,  
LAW Ming-Fan

Patent and Priority Information (Country, Number, Date):

Patent: WO 200035363 A1 20000622 (WO 0035363)  
Application: WO 99US29148 19991208 (PCT/WO US9929148)  
Priority Application: US 98211188 19981214  
Designated States:  
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)  
AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE  
GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK  
MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN  
YU ZA ZW AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE  
Publication Language: English  
Fulltext Word Count: 8548

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8/3,AU/13 (Item 13 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01180532  
GUIDEWIRE HAVING SIDEWISE LOOKING IMAGING CAPABILITIES AND METHOD  
FIL-GUIDE A SYSTEME D'IMAGERIE POUR VUE DE COTE ET PROCEDE CORRESPONDANT  
PATENT ASSIGNEE:  
Fox Hollow Technologies, (3055390), 3355 Edison Way, Menlo Park, CA 94025  
, (US), (Applicant designated States: all)  
INVENTOR:  
ORMSBY , Theodore , C., 2357 Dubois Street, Milpitas, CA 95035, (US)  
VAN BLADEL, Kevin, H., 1407 Carlisle Drive, San Mateo, CA 94402, (US)  
IMRAN, Mir, A., 26641 Laurel Lane, Los Altos, CA 94025, (US)  
PATENT (CC, No, Kind, Date):  
WO 200035349 000622  
APPLICATION (CC, No, Date): EP 99963100 991216; WO 99US30126 991216  
PRIORITY (CC, No, Date): US 216628 981216  
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;  
LU; MC; NL; PT; SE  
INTERNATIONAL PATENT CLASS: A61B-008/00  
LANGUAGE (Publication,Procedural,Application): English; English; English

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8/3,AU/14 (Item 14 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

00571976  
GUIDEWIRE HAVING SIDEWISE LOOKING IMAGING CAPABILITIES AND METHOD  
FIL-GUIDE A SYSTEME D'IMAGERIE POUR VUE DE COTE ET PROCEDE CORRESPONDANT  
Patent Applicant/Assignee:  
FOX HOLLOW TECHNOLOGIES INC,  
Inventor(s):  
ORMSBY Theodore C ,  
VAN BLADEL Kevin H,  
IMRAN Mir A  
Patent and Priority Information (Country, Number, Date):  
Patent: WO 200035349 A1 20000622 (WO 0035349)  
Application: WO 99US30126 19991216 (PCT/WO US9930126)  
Priority Application: US 98216628 19981216  
Designated States:  
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)  
AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB  
GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD

MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG  
UZ VN YU ZA ZW GH GM KE LS MW SD SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ  
TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI  
CM GA GN GW ML MR NE SN TD TG  
Publication Language: English  
Fulltext Word Count: 5166

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8/3,AU/15 (Item 15 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
(c) 2004 European Patent Office. All rts. reserv.

01140206  
APPARATUS AND METHOD FOR DEPLOYING A GUIDEWIRE ACROSS A COMPLEX LESION  
APPAREIL ET PROCEDE DE DEPLOIEMENT D'UN FIL-GUIDE D'UN COTE A L'AUTRE D'UNE  
LESION COMPLEXE

PATENT ASSIGNEE:

Fox Hollow Technologies, (2790500), 3355 Edison Way, Menlo Park, CA 94025  
, (US), (Applicant designated States: all)

INVENTOR:

IMRAN, Mir, A., 26641 Laurel Lane, Los Altos Hills, CA 94025, (US)  
ORMSBY, Theodore, C., 2357 Dubois Street, Milpitas, CA 95035, (US)  
SYKES, Carole, M., 928 Linden Avenue, Burlingame, CA 94010, (US)  
FRISBIE, Jeffrey, S., 3230 Maple Leaf Court, San Jose, CA 95121, (US)  
VAN BLADEL, Kevin, H., 1407 Carlisle Drive, San Mateo, CA 94402, (US)  
MCGILL, Scott, A., 114 Inner Circle, Redwood City, CA 94062, (US)  
KATOH, Osamu, 704 Daia Palace Royal Katsura, 43-1, Yamada Hirao-cho,  
Nishikyo-ku, Kyoto 615, (JP)

PATENT (CC, No, Kind, Date):

WO 200009020 000224

APPLICATION (CC, No, Date): EP 99942194 990813; WO 99US18526 990813

PRIORITY (CC, No, Date): US 134744 980814

DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;  
LU; MC; NL; PT; SE

INTERNATIONAL PATENT CLASS: A61B-017/22

LANGUAGE (Publication,Procedural,Application): English; English; English

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8/3,AU/16 (Item 16 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
(c) 2004 WIPO/Univentio. All rts. reserv.

00545647  
APPARATUS AND METHOD FOR DEPLOYING A GUIDEWIRE ACROSS A COMPLEX LESION  
APPAREIL ET PROCEDE DE DEPLOIEMENT D'UN FIL-GUIDE D'UN COTE A L'AUTRE D'UNE  
LESION COMPLEXE

Patent Applicant/Assignee:

REFLOW INC,

Inventor(s):

IMRAN Mir A,  
ORMSBY Theodore C ,  
SYKES Carole M,  
FRISBIE Jeffrey S,  
VAN BLADEL Kevin H,  
MCGILL Scott A,  
KATOH Osamu

Patent and Priority Information (Country, Number, Date):

Patent: WO 200009020 A1 20000224 (WO 0009020)

Application: WO 99US18526 19990813 (PCT/WO US9918526)

Priority Application: US 98134744 19980814

Designated States:

(Protection type is "patent" unless otherwise stated - for applications prior to 2004)

AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE  
GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK  
MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU  
ZA ZW GH GM KE LS MW SD SL SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH  
CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW  
ML MR NE SN TD TG

Publication Language: English

Fulltext Word Count: 14716

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8/3,AU/17 (Item 17 from file: 348)

DIALOG(R)File 348:EUROPEAN PATENTS

(c) 2004 European Patent Office. All rts. reserv.

00801711

Guiding introducer for use in the treatment of atrial flutter

Einführungshilfe zur Verwendung bei Vorhofflattern

Système d'introduction utilisable pour le traitement des flottements auriculaires

PATENT ASSIGNEE:

DAIG CORPORATION, (1027891), 14901 DeVeau Place, Minnetonka, Minnesota  
55345-2126, (US), (Proprietor designated states: all)

INVENTOR:

Swartz, John F., 2935 East 75th, Tulsa, Oklahoma 74136, (US)

Ockuly, John D., 14901 DeVeau Place, Minnetonka, MN 55345, (US)

Hassett, James A., 11327 Louisiana Circle, Bloomington, MN 55438, (US)

LEGAL REPRESENTATIVE:

Splanemann Reitzner Baronetzky Westendorp Patentanwälte (100431),  
Rumfordstrasse 7, 80469 München, (DE)

PATENT (CC, No, Kind, Date): EP 745407 A2 961204 (Basic)

EP 745407 A3 980624

EP 745407 B1 031119

APPLICATION (CC, No, Date): EP 96102198 960214;

PRIORITY (CC, No, Date): US 431787 950501

DESIGNATED STATES: AT; CH; DE; ES; FR; GB; IT; LI; NL; SE

INTERNATIONAL PATENT CLASS: A61M-025/01; A61M-025/00

ABSTRACT WORD COUNT: 71

NOTE:

Figure number on first page: 1C

LANGUAGE (Publication,Procedural,Application): English; English; English

FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
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CLAIMS A	(English)	EPAB96	695
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CLAIMS B	(English)	200347	718
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CLAIMS B	(German)	200347	725
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CLAIMS B	(French)	200347	792
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SPEC A	(English)	EPAB96	6741
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SPEC B	(English)	200347	6885
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Total word count - document A	7437
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Total word count - document B	9120
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Total word count - documents A + B	16557
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8/3,AU/18 (Item 18 from file: 349)

DIALOG(R)File 349:PCT FULLTEXT

(c) 2004 WIPO/Univentio. All rts. reserv.

01153087

↓ "wo" VERSION OF THIS APPLICATION

PREFORMED CATHETER SET FOR USE WITH A LINEAR ABLATION SYSTEM TO PRODUCE  
ABLATION LINES IN THE LEFT AND RIGHT ATRIUM FOR TREATMENT OF ATRIAL  
FIBRILLATION

ENSEMBLE CATHETER PREFORME A UTILISER AVEC UN SYSTEME D'ABLATION LINEAIRE  
DE FACON A PRODUIRE DES LIGNES D'ABLATION DANS L' ATRIUM GAUCHE ET  
DROIT POUR LE TRAITEMENT DE LA FIBRILLATION ATRIALE

Patent Applicant/Assignee:

MEDWAVES INC, 6215 Ferris Square Drive; Suite 100, San Diego, CA 92121,  
US, US (Residence), US (Nationality), (For all designated states  
except: US)

Patent Applicant/Inventor:

FELD Gregory K, 6215 Ferris Square Drive; Suite 100, San Diego, CA  
92121, US, US (Residence), US (Nationality), (Designated only for: US)  
ORMSBY Theodore C, 2357 Dubois Street, Milpitas, ca 95035, US, US  
(Residence), US (Nationality), (Designated only for: US)  
LAW Ming -Fan, 12344 Picrus Street, San Diego, CA 92129, US, US  
(Residence), US (Nationality), (Designated only for: US)  
LEUNG George L, 12516 Cloudesly Drive, San Diego, CA 92128, US, US  
(Residence), US (Nationality), (Designated only for: US)

Legal Representative:

BEUERLE Stephen C (agent), Procopio, Cory, Hargreaves & Savitch LLP, 530  
B Street; Suite 2100, San Diego, CA 92101-4469, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200473766 A2 20040902 (WO 0473766)  
Application: WO 2004US4693 20040219 (PCT/WO US04004693)  
Priority Application: US 2003449097 20030220; US 2004772861 20040206

Designated States:

(All protection types applied unless otherwise stated - for applications  
2004+)

AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM  
DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC  
LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO  
RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW  
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE  
SI SK TR

(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

(AP) BW GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW

(EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English

Filing Language: English

Fulltext Word Count: 4937

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8/3,AU/19 (Item 19 from file: 349)

DIALOG(R)File 349:PCT FULLTEXT

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01040091

ELECTROSURGICAL APPARATUS AND METHODS FOR TREATING JOINT TISSUE

APPAREIL D'ELECTROCHIRURGIE ET PROCEDES DE TRAITEMENT DE TISSU  
D'ARTICULATION

Patent Applicant/Assignee:

ARTHROCARE CORPORATION, 680 Vaqueros Avenue, Sunnyvale, CA 94085, US, US  
(Residence), US (Nationality)

Inventor(s):

WOLOSZKO Jean, 1694 Columbia Drive, Mountain View, CA 94040, US,  
DAVISON Terry S, 69 A Mirabel Avenue, San Francisco, CA 94110, US,  
ORMSBY Theodore C, 2357 Dubois Street, Milpitas, CA 95035, US

Legal Representative:

BAGADE Sanjay S (agent), ArthroCare Corporation, 680 Vaqueros Avenue,

Sunnyvale, CA 94085, US,  
Patent and Priority Information (Country, Number, Date):  
Patent: WO 200368311 A2-A3 20030821 (WO 0368311)  
Application: WO 2003US4689 20030213 (PCT/WO US03004689)  
Priority Application: US 2002357570 20020213  
Designated States:  
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)  
AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ  
EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR  
LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SC SD SE SG  
SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU ZA ZM ZW  
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT SE SI  
SK TR  
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG  
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW  
(EA) AM AZ BY KG KZ MD RU TJ TM  
Publication Language: English  
Filing Language: English  
Fulltext Word Count: 51015

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8/3,AU/20 (Item 20 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
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00843387

**FORMULATION FOR THE PREVENTION OF CARDIOVASCULAR DISEASE**  
**FORMULATION DESTINEE A LA PREVENTION DE MALADIES CARDIO -VASCULAIRES**

Patent Applicant/Inventor:

WALD Nicholas J, 22 Staverton Road, Oxford OX2 6XJ, GB, GB (Residence)  
GB (Nationality)  
LAW Malcolm R, 8 Grosvenor Gardens, London SW14 8BY, GB, GB (Residence)  
, GB (Nationality)

Legal Representative:

HALLYBONE Huw George (et al) (agent), Carpmaels & Ransford, 43 Bloomsbury  
Square, London WC1A 2RA, GB,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200176632 A1 20011018 (WO 0176632)  
Application: WO 2001GB1618 20010410 (PCT/WO GB0101618)  
Priority Application: GB 20008791 20000410; GB 2001548 20010109

Designated States:

(Protection type is "patent" unless otherwise stated - for applications prior to 2004)

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ  
EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS  
LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ  
TM TR TT TZ UA UG US UZ VN YU ZA ZW  
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR  
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG  
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW  
(EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English

Filing Language: English

Fulltext Word Count: 21512

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8/3,AU/21 (Item 21 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
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00561090

DIRECTIONAL REFLECTOR SHIELD ASSEMBLY FOR A MICROWAVE ABLATION INSTRUMENT  
ENSEMBLE ECRAN REFLECTEUR DIRECTIONNEL POUR INSTRUMENT D'ABLATION A  
HYPERFREQUENCES

Patent Applicant/Assignee:

FIDUS MEDICAL TECHNOLOGY CORPORATION,

Inventor(s):

BERUBE Dany,

WOODARD Robert E,

ORMSBY Theodore C

Patent and Priority Information (Country, Number, Date):

Patent: WO 200024463 A2 20000504 (WO 0024463)

Application: WO 99US24047 19991022 (PCT/WO US9924047)

Priority Application: US 98178066 19981023

Designated States:

(Protection type is "patent" unless otherwise stated - for applications  
prior to 2004)

AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

Publication Language: English

Fulltext Word Count: 7692

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Set	Items	Description
S1	5452	AU=(FELD G? OR FELD, G? OR ORMSBY T? OR ORMSBY, T? OR LAW - M? OR LAW, M? OR LAW MF OR LAW, MF OR LEUNG G? OR LEUNG, G?)
S2	18	GREG?(2N)FELD OR (THEODORE OR TED) (2N)ORMSBY OR MING?(2N)L-AW OR GEORGE(2N)LEUNG
S3	361292	(FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUTTER?) AND (ATRIU? OR ATRIA? OR CARDI?)
S4	303	S1:S2 AND S3
S5	94	S4 AND (ABLAT? OR RF OR RADIOFREQU? OR RADIO()FREQ? OR MICROWAV? OR ELECTRIC?()ISOLAT?)
S6	85	S5 AND (CATHETER? OR CANULA? OR CANNULA? OR CANNULA? OR C-ANULLA? OR LUMEN?)
S7	15	S6 AND (LINE? OR LINEAR? OR LESION? OR CURVIL? OR SCAR? OR ULCER? OR ANTENNA?)
S8	11	S7 AND PY<2004
S9	3	RD (unique items)

? show files

File 2:INSPEC 1969-2004/Sep W1  
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File 5:Biosis Previews(R) 1969-2004/Sep W2  
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File 6:NTIS 1964-2004/Sep W2  
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(c) 2004 FIZ TECHNIK

File 99:Wilson Appl. Sci & Tech Abs 1983-2004/Aug  
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File 155:MEDLINE(R) 1951-2004/Sep W2  
(c) format only 2004 The Dialog Corp.

File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec  
(c) 1998 Inst for Sci Info

File 481:DELPHEs Eur Bus 95-2004/Sep W1  
(c) 2004 ACFCI & Chambre CommInd Paris

File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13  
(c) 2002 The Gale Group

9/3,K/1 (Item 1 from file: 5)  
DIALOG(R) File 5: Biosis Previews(R)  
(c) 2004 BIOSIS. All rts. reserv.

0012298816 BIOSIS NO.: 200000017129

Evolution of diagnostic and interventional cardiac electrophysiology: A  
brief historical review

AUTHOR: Feld Gregory K (Reprint

AUTHOR ADDRESS: University of California-San Diego Medical Center, 200 West  
Arbor Drive, San Diego, CA, 92103, USA\*\*USA

JOURNAL: American Journal of Cardiology 84 (9A): p115R-124R Nov. 4, 1999  
1999

MEDIUM: print

ISSN: 0002-9149

DOCUMENT TYPE: Article; Literature Review

RECORD TYPE: Abstract

LANGUAGE: English

Evolution of diagnostic and interventional cardiac electrophysiology: A  
brief historical review

AUTHOR: Feld Gregory K ...

1999

ABSTRACT: The field of clinical cardiac electrophysiology has evolved  
dramatically over the last 30 years, beginning with description of the  
first...

...1970s, more sophisticated diagnostic electrophysiologic techniques were  
developed to diagnose and guide drug treatment of arrhythmias . These  
diagnostic techniques were further advanced during the late 1970s and  
1980s to electrically map arrhythmias and guide their surgical  
ablation . Surgical treatments of both supraventricular and ventricular  
arrhythmias proliferated in the 1970s and 1980s, with overall excellent  
results. However, because of the morbidity and mortality associated with  
arrhythmia surgery, it was ultimately replaced in the 1990s by radio -  
frequency catheter ablation (RFCA) for treatment of most forms of  
supraventricular tachycardia and idiopathic ventricular tachycardia ,  
and by the automatic implantable cardioverter defibrillator (ICD) for  
treatment of life-threatening ventricular arrhythmias associated with  
coronary artery disease and dilated cardiomyopathy . At present, the  
only arrhythmias that cannot be reliably and safely cured by RFCA are  
chronic atrial fibrillation and life-threatening ventricular  
arrhythmias . For chronic atrial fibrillation , new catheter designs  
are being developed to create linear ablation lines mimicking the  
curative MAZE operation. For life-threatening ventricular arrhythmias ,  
the ICD has been increasingly utilized as transvenous lead systems and  
smaller devices have been developed. In the next millennium, new  
developments that may be expected for treatment of atrial fibrillation  
and life-threatening ventricular arrhythmias include catheter  
systems for linear RFCA of atrial fibrillation , ICDs for both  
atrial and ventricular defibrillation, and biventricular pacing ICDs for  
patients with congestive heart failure.

DESCRIPTORS:

...MAJOR CONCEPTS: Cardiovascular Medicine

DISEASES: arrhythmia --...

... atrial fibrillation --...

...dilated cardiomyopathy --...

...supraventricular arrhythmia --...

...ventricular arrhythmia --  
MESH TERMS: Arrhythmia (MeSH...  
... Atrial Fibrillation (MeSH...

... Cardiomyopathy , Congestive (MeSH...

... Tachycardia , Supraventricular (MeSH...

... Tachycardia , Supraventricular (MeSH)  
...METHODS & EQUIPMENT: atrial , therapeutic method, ventricular...

... radiofrequency catheter ablation {RFCA...

...complications, linear catheter design, surgical method,  
therapeutic method...

...surgical ablation --  
MISCELLANEOUS TERMS: clinical cardiac electrophysiology...

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9/3,K/2 (Item 2 from file: 5)  
DIALOG(R) File 5: Biosis Previews(R)  
(c) 2004 BIOSIS. All rts. reserv.

0012043169 BIOSIS NO.: 199900302829

**Right atrial compartmentalization using radiofrequency catheter ablation for management of patients with refractory atrial fibrillation**

AUTHOR: Garg Ashok; Finneran William; Mollerus Michael; Birgersdotter-Green Ulrika; Fujimura Osamu; Tone Linda; **Feld Gregory K** (Reprint

AUTHOR ADDRESS: Electrophysiology Program, Division of Cardiology, Department of Medicine, University of California, 200 W. Arbor Dr., San Diego, CA, 92103, USA\*\*USA

JOURNAL: Journal of Cardiovascular Electrophysiology 10 (6): p763-771  
June, 1999 1999

MEDIUM: print

ISSN: 1045-3873

DOCUMENT TYPE: Article

RECORD TYPE: Abstract

LANGUAGE: English

**Right atrial compartmentalization using radiofrequency catheter ablation for management of patients with refractory atrial fibrillation**

...AUTHOR: **Feld Gregory K**  
1999

ABSTRACT: **Ablation of Atrial Fibrillation**. Introduction: **Atrial fibrillation** (AF) is often refractory to antiarrhythmic drugs, and patients who are intolerant of AF may require the maze operation for cure. As a less invasive alternative, a **catheter**-based, **right atrial** compartmentalization procedure was evaluated. Methods and Results: Twelve patients with AF refractory to Class I and III antiarrhythmic drugs were studied. Four **linear right atrial radiofrequency ablations** were performed, from superior to inferior vena cava in the posterior wall and interatrial septum...

...tricuspid annulus through the appendage, and across the tricuspid valve-inferior vena cava isthmus. The **radiofrequency catheter** was dragged along each **line** three to four times, until the **atrial** electrogram amplitude decreased by 75% and there was bidirectional conduction block in the tricuspid valve...

...and 4 did not. Thus, 8 of 12 patients (67%) had suppression of AF after **ablation** on previously ineffective medication or no medication.

Conclusion: **Right atrial** compartmentalization may alter the substrate for AF, thus improving the efficacy of previously ineffective antiarrhythmic...

DESCRIPTORS:

MAJOR CONCEPTS: **Cardiovascular** Medicine...

DISEASES: **arrhythmia** --...

...refractory **atrial fibrillation** --

MESH TERMS: **Arrhythmia** (MeSH)

METHODS & EQUIPMENT: **radiofrequency catheter ablation** --...

...right **atrial** compartmentalization

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9/3,K/3 (Item 1 from file: 34)  
DIALOG(R)File 34:SciSearch(R) Cited Ref Sci  
(c) 2004 Inst for Sci Info. All rts. reserv.

09107666 Genuine Article#: 368GU No. References: 28

**Title:** Transcatheter cryoablation of ventricular myocardium in dogs

**Author(s):** Wadhwa MK; Rahme MM; Dobak J; Li H; Wolf P; Chen P; Feld GK  
(REPRINT)

**Corporate Source:** 200 W ARBOR DR,/SAN DIEGO//CA/92103 (REPRINT); UNIV CALIF  
SAN DIEGO,DEPT MED, DIV CARDIOL/SAN DIEGO//CA/92103

**Journal:** JOURNAL OF INTERVENTIONAL CARDIAC ELECTROPHYSIOLOGY, 2000 , V4,  
N3 (OCT), P537-545

**ISSN:** 1383-875X **Publication date:** 20001000

**Publisher:** KLUWER ACADEMIC PUBL, SPUIBOULEVARD 50, PO BOX 17, 3300 AA  
DORDRECHT, NETHERLANDS

**Language:** English **Document Type:** ARTICLE (ABSTRACT AVAILABLE)

**Author(s):** Wadhwa MK; Rahme MM; Dobak J; Li H; Wolf P; Chen P; Feld GK  
(REPRINT)

, 2000

...Abstract: a highly effective technique used during antiarrhythmic surgery, produces voluminous, histologically uniform and discreet myocardial lesions. In contrast, radiofrequency (RF) catheter ablation, which as a result of its less invasive nature has largely supplanted antiarrhythmic surgery, produces smaller, histologically heterogeneous myocardial lesions. Since small lesion size and heterogeneity may reduce antiarrhythmic efficacy, we sought to reproduce the large, histologically homogeneous lesions created by surgical cryoablation, using a catheter cryoablation system (Cryogen, Inc., San Diego, CA) in the canine ventricle.

**Methods and Results:** In seven dogs, nineteen ventricular lesions (two right and seventeen left) were created with a 10F cryoablation catheter with either a 2 or 6 mm tip. In one dog AV node ablation was also performed. For each 'freeze', catheter tip nadir temperature, lesion width, depth, and transmuralty were recorded, and lesion volume calculated. Average tip nadir temperature was  $-79.6 \pm 4.9$  degreesC. Cooler nadir tip temperature was associated with deeper ( $p=.007$ ) and more voluminous lesions ( $p=.042$ ), and a greater likelihood of lesion transmuralty ( $p=.034$ ). Average lesion volume was  $500 \pm 356$  mm<sup>3</sup>. No other variables predicted lesion volume or transmuralty. Histologically, the catheter cryoablation lesions were sharply demarcated and homogeneous. The single freeze performed at the AV junction produced complete AV block. One complication, catheter rupture following its repetitive use, resulted in a coronary air embolus and death.

**Conclusion:** Catheter cryoablation of canine ventricular myocardium produced voluminous, discrete, transmural lesions, which might be effective for ablation of ventricular tachycardia. Lesion volume and transmuralty were dependent on catheter tip nadir temperature.

...Identifiers-- RADIOFREQUENCY CATHETER ABLATION ; ATRIOVENTRICULAR JUNCTION; REENTRANT TACHYCARDIA ; CRYOSURGICAL ABLATION ; CARDIAC - ARRHYTHMIAS ; AV NODE; HEART; ELECTROPHYSIOLOGY; DESICCATION; DIMENSIONS

Set	Items	Description
S1	139	AU=(FELD G? OR FELD, G? OR ORMSBY T? OR ORMSBY, T? OR LAW - M? OR LAW, M? OR LAW MF OR LAW, MF OR LEUNG G? OR LEUNG, G?)
S2	502	GREG?(2N)FELD OR (THEODORE OR TED) (2N)ORMSBY OR MING?(2N)L-AW OR GEORGE(2N)LEUNG
S3	34629	(FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUTTER?) AND (ATRIU? OR ATRIA? OR CARDI?)
S4	19	S1:S2 AND S3
? show files		
File	9:Business & Industry(R)	Jul/1994-2004/Sep 15 (c) 2004 The Gale Group
File	15:ABI/Inform(R)	1971-2004/Sep 16 (c) 2004 ProQuest Info&Learning
File	16:Gale Group PROMT(R)	1990-2004/Sep 16 (c) 2004 The Gale Group
File	43:Health News Daily - Subs	1990-2004/Sep 15 (c) 2004 F-D-C reports Inc.
File	47:Gale Group Magazine DB(TM)	1959-2004/Sep 16 (c) 2004 The Gale group
File	98:General Sci Abs/Full-Text	1984-2004/Jul (c) 2004 The HW Wilson Co.
File	129:PHIND(Archival)	1980-2004/Sep W1 (c) 2004 PJB Publications, Ltd.
File	130:PHIND(Daily & Current)	2004/Sep 16 (c) 2004 PJB Publications, Ltd.
File	135:NewsRx Weekly Reports	1995-2004/Sep W2 (c) 2004 NewsRx
File	148:Gale Group Trade & Industry DB	1976-2004/Sep 16 (c)2004 The Gale Group
File	149:TGG Health&Wellness DB(SM)	1976-2004/Aug W4 (c) 2004 The Gale Group
File	160:Gale Group PROMT(R)	1972-1989 (c) 1999 The Gale Group
File	369:New Scientist	1994-2004/Sep W1 (c) 2004 Reed Business Information Ltd.
File	370:Science	1996-1999/Jul W3 (c) 1999 AAAS
File	441:ESPICOM Pharm&Med DEVICE NEWS	2004/Sep W2 (c) 2004 ESPICOM Bus.Intell.
File	444:New England Journal of Med.	1985-2004/Sep W2 (c) 2004 Mass. Med. Soc.
File	621:Gale Group New Prod. Annou. (R)	1985-2004/Sep 16 (c) 2004 The Gale Group
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4/3,K/1 (Item 1 from file: 16)  
DIALOG(R)File 16:Gale Group PROMT(R)  
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06788796 Supplier Number: 57395502 (USE FORMAT 7 FOR FULLTEXT)  
**New Findings Indicate Potential Efficacy of Cryoablation in Treating Irregular Heartbeat.**  
Business Wire, p0444  
Nov 8, 1999  
Language: English Record Type: Fulltext  
Document Type: Newswire; Trade  
Word Count: 583

... lesions in the heart wall, may offer physicians promise in correcting certain electrical conduction disorders ( **arrhythmias** ) in the heart. **Arrhythmias** that cause rapid heartbeats, such as ventricular **tachycardia** (VT), diminish the heart's pumping efficiency and may cause patients to feel lightheaded, experience palpitations, or even faint. These **arrhythmias** are often lethal and more than 250,000 new cases are diagnosed in the U...

...the transcatheter cryoablation study, which was led by University of California San Diego (UCSD) physician **Gregory K. Feld**, M.D., professor of medicine and director of the **cardiac** electrophysiology programs, was to establish the safety and efficacy of cryoablation in animal studies. Currently...

...by this technology may not penetrate deep enough into the heart tissue to cure the **arrhythmia**. Additionally, the heat caused by the RF procedure can cause tissue charring and clotting. These...

...look forward to future investigation of this procedure and its potential benefits for patients with **cardiac arrhythmias**."

Transcatheter cryoablation findings indicate that physicians using this technology can correct electrical conduction disorders by...

...medical device company focused on the introduction of a novel cryoablation technology for gynecology and **cardiology**. CryoGen has developed a miniature, closed-cycle cryoablation device and supporting system that enables physicians...

4/3,K/2 (Item 2 from file: 16)  
DIALOG(R)File 16:Gale Group PROMT(R)  
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04997541 Supplier Number: 47339313 (USE FORMAT 7 FOR FULLTEXT)  
**Microwave ablation contributes to successful treatment of atrial flutter**  
Business Wire, p04300341  
April 30, 1997  
Language: English Record Type: Fulltext  
Document Type: Newswire; Trade  
Word Count: 309

(USE FORMAT 7 FOR FULLTEXT)  
**Microwave ablation contributes to successful treatment of atrial flutter**

TEXT:

...time, its microwave catheter ablation systems made a major contribution



to the successful treatment of **atrial flutter** in a patient.

... de Montreal, Montreal, Canada reported this significant therapeutic breakthrough in an ablation procedure to cure **atrial flutter**. The procedure used a catheter system which delivered controlled microwave energy to carefully targeted tissue...

...long linear lesions, Dr. Molin created a lesion across the targeted tissue within the right **atrium** of his patient's heart.

After the creation of the primary lesion with the experimental...

...complete the lesion. This lesion interdicted the abnormal electrical circuit which is the cause of **atrial flutter**.

**Atrial flutter**, a serious **cardiac tachycardia** (abnormally rapid beating of the heart), reduces **cardiac** output by up to 25% and is difficult to treat with drugs. **Atrial flutter** typically degenerates into dangerous **atrial fibrillation** which is associated with a five times increased risk of stroke. In the United States, approximately 200,000 patients suffer from **atrial flutter** and 25,000 new cases arise each year.

**Ted Ormsby**, vice president of engineering at Fidus, who assisted in the procedure, stated that this advance is another milestone in the continuous development of microwave catheters to treat **atrial flutter** and **atrial fibrillation**. Clinical studies are being conducted in North America and Europe to further evaluate and improve...

...Medical Technology Corp. designs, develops and manufactures minimally invasive microwave ablation systems to treat major **cardiac arrhythmias**. Fidus is located at 47929 Fremont Blvd., Fremont, CA 94538. Phone is 510/651-7430. -0-

Keywords: **Cardiology**, **Cardiovascular** devices.

CONTACT: Fidus Medical Technology  
David V. Robson, 510/651-7430

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4/3,K/3 (Item 3 from file: 16)

DIALOG(R)File 16:Gale Group PROMT(R)

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04352553 Supplier Number: 46383717 (USE FORMAT 7 FOR FULLTEXT)  
**FIDUS MEDICAL TECHNOLOGY CORPORATION ANNOUNCES THE SUBMISSION OF THE INVESTIGATIONAL DEVICE EXEMPTION (IDE) TO FDA FOR REVIEW**

PR Newswire, p0513SFM014

May 13, 1996

Language: English Record Type: Fulltext

Document Type: Newswire; Trade

Word Count: 361

(USE FORMAT 7 FOR FULLTEXT)

TEXT:

FDA Reviewing Microwave **Cardiac** Ablation System for Initiating a Human Study in the U.S., Which Could Prevent **Cardiac** Arrest and Cure 20% of

U.S. Population from **Arrhythmias**

FREMONT, Calif., May 13 /PRNewswire/ -- Fidus Medical Technology submitted an IDE application to FDA for approval of the **Cardiovascular** Microwave Ablation System to treat heart **arrhythmia** patients. Fidus announced today that the FDA has started to review the IDE application submitted...

...catheters and microwave power systems, to advance the medical technology

and patient care in treating **cardiac arrhythmia** .

**Cardiac arrhythmias** are a recurring condition in which the heart's normal electrical impulses are disrupted, causing irregular or rapid heartbeats ( **arrhythmia** ). Nearly 500,000 people die each year from **arrhythmias** , which can be caused by heart attacks, high blood pressure, as well as the natural...

...S. population ultimately develops some type of irregular heartbeat problem during their lives. Using a **cardiac** microwave ablation system, the faulty heart cells causing the **arrhythmias** are heated and eliminated (ablated), stopping the abnormal impulses. Without treatment, various **arrhythmias** can cause chronic lack of energy, racing heart, dizziness, nausea, shortness of breath, chest pain...

...offers several advantages over the radio-frequency (RF) ablation system currently being used to perform **cardiac** ablation procedures. The Fidus microwave system can control the ablation size, which is necessary to cure several types of **arrhythmias** . **Atrial fibrillation** requires a long linear lesion (burn) and ventricular **tachycardia** requires volumetrically larger lesion. "These two very common conditions now potentially can be cured with...

...in technology. This is much more powerful," said Dr. L. Bing Liem, associate director of **Cardiac** Electrophysiology and **Arrhythmia** Services at Stanford University Medical Center. "That's the excitement here." The Fidus **Cardiovascular** Microwave Ablation System has the potential to treat these types of **arrhythmias** .

-0-

5/13/96

/CONTACT: **Theodore Ormsby** , technology and development department of FIDUS Medical Technology, 510-651-7430, or fax, 510-651...  
PRODUCT NAMES: 3841540 ( **Cardiovascular** Therapy Equip)

4/3,K/4 (Item 1 from file: 135)  
DIALOG(R)File 135:NewsRx Weekly Reports  
(c) 2004 NewsRx. All rts. reserv.

0000105210 (USE FORMAT 7 OR 9 FOR FULLTEXT)  
**FDA approves EPT-1000 XP cardiac ablation system**  
Biotech Week, September 24, 2003, p.73

DOCUMENT TYPE: Expanded Reporting LANGUAGE: English  
RECORD TYPE: FULLTEXT  
WORD COUNT: 443

VATZ

**FDA approves EPT-1000 XP cardiac ablation system**

...TEXT: PMA) from the U.S. Food and Drug Administration (FDA) for its EPT-1000 XP **Cardiac** Ablation System for the treatment of **atrial flutter** .

It has been estimated that there are more than 200,000 new patients diagnosed with **atrial flutter** each year in the United States. The abnormal electrical signal causing **atrial flutter** occurs in the right **atrium** , in a circular pattern. Successful ablation procedures occur when a linear lesion is created across...

...directional manner, allowing the heart to return to normal rhythm permanently. The EPT-1000 XP **Cardiac** Ablation System allows for 8-mm and 10-mm tip electrodes to be used with up to 100 watts of radiofrequency energy to treat **atrial flutter** .

The EPT-1000 XP **Cardiac** Ablation system provides increased benefit in the treatment of patients with **atrial flutter**," said **Gregory Feld**, MD, professor of medicine, director of the Electrophysiology Program at the University of California San Diego Medical Center and principal investigator of the clinical trial.

"Our experience in treating **atrial flutter** shows an advantage to using a 10 mm tip electrode, such as the BLAZER II..."

...multicenter study show shorter procedure times with fewer ablations and a chronic success rate for **atrial flutter** in excess of 96%. At present Boston Scientific is the only company that has developed...

...have received approval for the first 100-watt radiofrequency system used in the treatment of **atrial flutter**," said Tom Coen, president of Boston Scientific's Electrophysiology business. "Evolutionary in design, the EPT ...

...medical director at Boston Scientific, noted that "From our clinical trial study results, patients with **atrial flutter** who had an ablation with the EPT-1000XP **Cardiac** Ablation System demonstrated a dramatic improvement in their quality of life 1 month after the...

...persisted through the 6-month measurement period. They also displayed a marked reduction in both **arrhythmia** -related symptoms and the use of medications to treat this condition."

This article was prepared...

DESCRIPTORS: Boston Scientific Corp.; Therapy; **Cardiology** ; All News ; Consumer News; Biotechweek

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4/3,K/5 (Item 2 from file: 135)  
DIALOG(R)File 135:NewsRx Weekly Reports  
(c) 2004 NewsRx. All rts. reserv.

0000068834 (USE FORMAT 7 OR 9 FOR FULLTEXT)  
**Progress made in efforts to obtain FDA approval of cardiac ablation system**  
Medical Devices & Surgical Technology Week, November 3, 2002, p.9

DOCUMENT TYPE: Expanded Reporting LANGUAGE: English  
RECORD TYPE: FULLTEXT  
WORD COUNT: 597

**Progress made in efforts to obtain FDA approval of cardiac ablation system**

...TEXT: PMA) from the U.S. Food and Drug Administration (FDA) for its EPT-1000 XP **cardiac** ablation system for the treatment of **atrial flutter** .

Six of the seven PMA modules submitted by the company have been reviewed, accepted, and...

**Atrial flutter** is an abnormally rapid heartbeat that arises from the upper chambers of the heart and may cause significant symptoms and serious complications. The symptoms associated with **atrial flutter** include palpitations, shortness of breath, chest pain, fatigue, and occasionally the transient loss of consciousness.

**Atrial flutter** may cause serious complications including heart failure and stroke. Every year there are more than 200,000 new patients with **atrial flutter** in the United States. The EPT- 1000 XP **cardiac**

ablation system uses radiofrequency (RF) to treat this condition by creating a linear lesion across the tricuspid isthmus, interrupting the abnormal electrical circuit causing the **atrial flutter** and allowing the heart to return to normal rhythm.

Historically, patients with **atrial flutter** have been treated using a variety of methods such as electrical **cardioversion** and antiarrhythmic drugs. However, these approaches are palliative and the **arrhythmia** may require alternative treatment. RF **cardiac** ablation offers a viable alternative to these palliative treatments.

"The EPT-1000 XP **cardiac** ablation system provides increased benefit in the treatment of patients with **atrial flutter**," said **Gregory Feld**, professor of medicine, director of the Electrophysiology Program at the University of California San Diego Medical Center and principal investigator of Boston Scientific's **atrial flutter** study. "Our experience in treating **atrial flutter** shows a definite advantage to using a 10mm tip catheter, such as the BLAZER II...

...dramatic improvement in their quality of life after being treated with the EPT-1000 XP **cardiac** ablation system."

The Boston Scientific **atrial flutter** system consists of a family of BLAZER II XP bi-directional, temperature-controlled **cardiac** ablation catheters and the EPT-1000 XP generator. While the new EPT-1000 XP generator...

...same as the currently available EPT-1000 generator installed in the majority of U.S. **cardiac** ablation centers, the forthcoming version will increase the available RF power level from 50 to...

...with the latest technology should result in rapid market adoption and our continued leadership in **cardiac** ablation."

This article was prepared by Medical Devices & Surgical Technology Week editors from staff and...

DESCRIPTORS: **Cardiology ; Therapy; All News; Consumer News**  
SUBJECT HEADING: **Atrial Flutter**

4/3,K/6 (Item 1 from file: 148)  
DIALOG(R)File 148:Gale Group Trade & Industry DB  
(c)2004 The Gale Group. All rts. reserv.

14899506 SUPPLIER NUMBER: 90192478 (USE FORMAT 7 OR 9 FOR FULL TEXT)  
Sudden headache in a woman with hypertension. (What's Wrong with this Picture?).

Quick, Gary; **Law, Maggie**  
Consultant, 42, 8, 1049(3)  
July, 2002

ISSN: 0010-7069 LANGUAGE: English RECORD TYPE: Fulltext  
WORD COUNT: 1371 LINE COUNT: 00113

... **Law, Maggie**

... results are normal except for trace blood and trace protein. The chest film shows no **cardiomegaly** or congestive heart failure; the ECG reveals evidence of left ventricular hypertrophy, left axis deviation...the BP at 160/100 mm Hg. She experiences an 8-beat episode of ventricular **tachycardia** without chest pain or altered consciousness. ICH is thought to be the cause of the...The patient undergoes a dipyridamole stress test on day 4. This study is negative for **cardiac** ischemia and reveals an ejection fraction of 50%. A carotid ultrasound scan performed on day...

*DISREGARD*

4/3,K/7 (Item 2 from file: 148)  
DIALOG(R)File 148:Gale Group Trade & Industry DB  
(c)2004 The Gale Group. All rts. reserv.

11475185 SUPPLIER NUMBER: 57395502 (USE FORMAT 7 OR 9 FOR FULL TEXT)  
**New Findings Indicate Potential Efficacy of Cryoablation in Treating**

**Irregular Heartbeat.**

Business Wire, 0444

Nov 8, 1999

LANGUAGE: English RECORD TYPE: Fulltext

WORD COUNT: 625 LINE COUNT: 00057

... lesions in the heart wall, may offer physicians promise in correcting certain electrical conduction disorders ( **arrhythmias** ) in the heart. **Arrhythmias** that cause rapid heartbeats, such as ventricular **tachycardia** (VT), diminish the heart's pumping efficiency and may cause patients to feel lightheaded, experience palpitations, or even faint. These **arrhythmias** are often lethal and more than 250,000 new cases are diagnosed in the U...

...the transcatheter cryoablation study, which was led by University of California San Diego (UCSD) physician **Gregory K. Feld**, M.D., professor of medicine and director of the **cardiac** electrophysiology programs, was to establish the safety and efficacy of cryoablation in animal studies. Currently...

...by this technology may not penetrate deep enough into the heart tissue to cure the **arrhythmia**. Additionally, the heat caused by the RF procedure can cause tissue charring and clotting. These...

...look forward to future investigation of this procedure and its potential benefits for patients with **cardiac arrhythmias**."

Transcatheter cryoablation findings indicate that physicians using this technology can correct electrical conduction disorders by...

...medical device company focused on the introduction of a novel cryoablation technology for gynecology and **cardiology**. CryoGen has developed a miniature, closed-cycle cryoablation device and supporting system that enables physicians...

4/3,K/8 (Item 3 from file: 148)  
DIALOG(R)File 148:Gale Group Trade & Industry DB  
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09749436 SUPPLIER NUMBER: 19781494 (USE FORMAT 7 OR 9 FOR FULL TEXT)  
**Fidus Medical Technology Reports Record Clinical Success in the Treatment**

**of Atrial Flutter Using Its Microwave Cardiac Ablation System**

PR Newswire, p924SFW018

Sep 24, 1997

LANGUAGE: English RECORD TYPE: Fulltext

WORD COUNT: 410 LINE COUNT: 00040

**Fidus Medical Technology Reports Record Clinical Success in the Treatment of Atrial Flutter Using Its Microwave Cardiac Ablation System**

... Fidus Medical Technology Corporation today announced that its microwave catheter ablation system continues to cure **atrial flutter**: At the Santa Cruz Hospital, Lisbon, Portugal, Dr. Pedro Adagao reported a successful ablation procedure that cured **atrial flutter** with a single microwave energy application.

Fidus is conducting an international multi-site program to produce linear lesions aimed at developing a cure for **atrial fibrillation**. Dr. Adagao used a microwave catheter ablation system that delivered controlled microwave energy to carefully...

...the tricuspid annulus. This lesion interrupted the abnormal electrical circuit that is the cause of **atrial flutter**. The patient, a 52 year-old male, was in **flutter** rhythm at the onset of the procedure. Approximately one minute into the ablation, the ECG monitor showed the transition from A-Flutter to a normal sinus rhythm. Dr. Adagao remarked, "We could successfully treat a patient with chronic **atrial flutter** with just one microwave application. The **atrial flutter** has been sustained for more than one year, refractory to several antiarrhythmic drugs and electrical cardioversion." Assisting Dr. Adagao was Dr. Francisco Morgado, Dr. Leonor Parreira and Dr. Daniel Bonhorst.

**Atrial flutter**, a serious **tachycardia** (abnormally rapid beating of the heart), reduces **cardiac** output by up to 25% and is difficult to treat with drugs. **Atrial flutter** typically degenerates into dangerous **atrial fibrillation** that is associated with a 5 fold increased risk of stroke. In the United States, approximately 2,500,000 patients suffer from **atrial fibrillation** and additional 200,000 new cases arise each year.

Ted Ormsby, Vice President of R&D and Technology of Fidus Medical stated that "the linear lesion capability of microwave ablation system is an important feature needed to address **atrial - fibrillation**".

Fidus Medical Technology Corporation develops and manufactures minimally invasive microwave ablation systems to treat major **cardiac arrhythmias**.

SOURCE Fidus Medical Technology Corporation

-0-

09/24/97

/CONTACT: Fred Seddiqui, President and CEO...

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4/3,K/9 (Item 4 from file: 148)

DIALOG(R)File 148:Gale Group Trade & Industry DB  
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09708458 SUPPLIER NUMBER: 19724849 (USE FORMAT 7 OR 9 FOR FULL TEXT)

Fidus Medical Technology Reports Microwave Ablation Continues to

Successfully Cure Arrhythmia Patients

PR Newswire, p905SFF013

Sep 5, 1997

LANGUAGE: English RECORD TYPE: Fulltext

WORD COUNT: 371 LINE COUNT: 00036

... Fidus Medical Technology Corporation today announced that its microwave catheter ablation system continues to cure **atrial flutter**: at the Hopital de Sacre-Coeur de Montreal, Montreal, Canada, Dr. Franck Molin reported a successful ablation procedure which cured **atrial flutter**.

Fidus is conducting an international multi-site program to produce linear lesions aimed at developing a cure for **atrial fibrillation**. Dr. Molin's most recent procedure used a microwave catheter ablation system which delivered controlled...

...linear lesions, Dr. Molin created a lesion across the IVC-TV Isthmus within the right **atrium** of his patient's heart. This lesion interrupts the abnormal electrical circuit which is the cause of **atrial flutter**. Dr. Molin remarked that "the procedure took less time than normally experienced with RF. After...

...line block was created in the isthmus." The total procedure time was

approximately one hour.

**Atrial flutter**, a serious **tachycardia** (abnormally rapid beating of the heart), reduces **cardiac** output by up to 25% and is difficult to treat with drugs. **Atrial flutter** typically degenerates into dangerous **atrial fibrillation** which is associated with a 5 times increased risk of stroke. In the United States, approximately 2,500,000 patients suffer from **atrial fibrillation** and another 200,000 new cases arise each year.

Ted Ormsby, Vice President of R&D and Technology at Fidus, stated that "this is a continuous validation in the use of a catheterized microwave ablation system for the successful treatment of **atrial flutter** and **fibrillation**. In cases where microwave has been used, we clearly see a competitive advantage over RF...

...Medical Technology Corporation designs, develops and manufactures minimally invasive microwave ablation systems to treat major **cardiac arrhythmias**.

SOURCE Fidus Medical Technology Corporation

-0-

09/05/97

/CONTACT: Fred Seddiqui, President and CEO...

DESCRIPTORS: **Cardiovascular** equipment industry...

PRODUCT/INDUSTRY NAMES: 3841540 ( **Cardiovascular** Therapy Equip)

4/3,K/10 (Item 5 from file: 148)

DIALOG(R)File 148:Gale Group Trade & Industry DB

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08661139 SUPPLIER NUMBER: 18284817 (USE FORMAT 7 OR 9 FOR FULL TEXT)

FIDUS MEDICAL TECHNOLOGY CORPORATION ANNOUNCES THE SUBMISSION OF THE  
INVESTIGATIONAL DEVICE EXEMPTION (IDE) TO FDA FOR REVIEW

PR Newswire, p513SFM014

May 13, 1996

LANGUAGE: English RECORD TYPE: Fulltext

WORD COUNT: 380 LINE COUNT: 00037

TEXT:

FDA Reviewing Microwave **Cardiac** Ablation System for Initiating a Human

Study in the U.S., Which Could Prevent **Cardiac** Arrest and Cure 20% of

U.S. Population from **Arrhythmias**

FREMONT, Calif., May 13 /PRNewswire/ -- Fidus Medical Technology submitted an IDE application to FDA for approval of the **Cardiovascular** Microwave Ablation System to treat heart **arrhythmia** patients. Fidus announced today that the FDA has started to review the IDE application submitted...

...catheters and microwave power systems, to advance the medical technology and patient care in treating **cardiac arrhythmia**.

**Cardiac arrhythmias** are a recurring condition in which the heart's normal electrical impulses are disrupted, causing irregular or rapid heartbeats ( **arrhythmia** ). Nearly 500,000 people die each year from **arrhythmias**, which can be caused by heart attacks, high blood pressure, as well as the natural...

...S. population ultimately develops some type of irregular heartbeat problem during their lives. Using a **cardiac** microwave ablation system, the faulty heart cells causing the **arrhythmias** are heated and eliminated (ablated), stopping the abnormal impulses. Without treatment, various

**arrhythmias** can cause chronic lack of energy, racing heart, dizziness, nausea, shortness of breath, chest pain...

...offers several advantages over the radio-frequency (RF) ablation system currently being used to perform **cardiac** ablation procedures. The Fidus microwave system can control the ablation size, which is necessary to cure several types of **arrhythmias**. **Atrial fibrillation** requires a long linear lesion (burn) and ventricular **tachycardia** requires volumetrically larger lesion. "These two very common conditions now potentially can be cured with...

...in technology. This is much more powerful," said Dr. L. Bing Liem, associate director of **Cardiac** Electrophysiology and **Arrhythmia** Services at Stanford University Medical Center. "That's the excitement here." The Fidus **Cardiovascular** Microwave Ablation System has the potential to treat these types of **arrhythmias**.

-0-

5/13/96

/CONTACT: **Theodore Ormsby**, technology and development department of FIDUS Medical Technology, 510-651-7430, or fax, 510-651...

DESCRIPTORS: **Cardiovascular** equipment industry...

PRODUCT/INDUSTRY NAMES: 3841540 ( **Cardiovascular** Therapy Equip...

4/3,K/11 (Item 1 from file: 149)

DIALOG(R)File 149:TGG Health&Wellness DB(SM)

(c) 2004 The Gale Group. All rts. reserv.

02098798 SUPPLIER NUMBER: 90192478 (USE FORMAT 7 OR 9 FOR FULL TEXT)

Sudden headache in a woman with hypertension. (What's Wrong with this Picture?).

Quick, Gary; **Law, Maggie**

Consultant, 42, 8, 1049(3)

July,

2002

PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 0010-7069

LANGUAGE: English RECORD TYPE: Fulltext TARGET AUDIENCE: Professional

WORD COUNT: 1371 LINE COUNT: 00113

... **Law, Maggie**

... results are normal except for trace blood and trace protein. The chest film shows no **cardiomegaly** or congestive heart failure; the ECG reveals evidence of left ventricular hypertrophy, left axis deviation...

...the BP at 160/100 mm Hg. She experiences an 8-beat episode of ventricular **tachycardia** without chest pain or altered consciousness. ICH is thought to be the cause of the...

...The patient undergoes a dipyridamole stress test on day 4. This study is negative for **cardiac** ischemia and reveals an ejection fraction of 50%. A carotid ultrasound scan performed on day...

4/3,K/12 (Item 2 from file: 149)

DIALOG(R)File 149:TGG Health&Wellness DB(SM)

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01969036 SUPPLIER NUMBER: 70455912

A novel genetic pathway for sudden cardiac death via defects in the transition between ventricular and conduction system cell lineages. (Statistical Data Included)

DISREGARD



Nguyen-Tran, Van T.B.; Kubalak, Steven W.; Minamisawa, Susumu; Fiset, Celine; Wollert, Kai C.; Brown, Anne B.; Ruiz-Lozano, Pilar; Barrere-Lemaire, Stephanie; Kondo, Richard; Norman, Lisa W.; Gourdie, Robert G.; Rahme, Marc M.; **Feld, Gregory K.** ; Clark, Robert B.; Giles, Wayne R.; Chien, Kenneth R  
Cell, 102, 5, 671(12)  
Sept 1,  
2000

DOCUMENT TYPE: Statistical Data Included PUBLICATION FORMAT:  
Magazine/Journal; Refereed ISSN: 0092-8674 LANGUAGE: English  
RECORD TYPE: Abstract TARGET AUDIENCE: Academic

**A novel genetic pathway for sudden cardiac death via defects in the transition between ventricular and conduction system cell lineages. (Statistical Data...**  
... **Feld, Gregory K**

ABSTRACT: Research demonstrates that the HF-1b transcription factor of **cardiac** conduction system and ventricular myocytes play a role in the sudden **cardiac** death in humans. Data reveal that the **cardiovascular** arrest is due to **cardiac arrhythmogenesis** brought about by a decrease and mislocalization of connexins and defects in the formation of...

DESCRIPTORS: **Cardiac arrest...**

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4/3,K/13 (Item 3 from file: 149)

DIALOG(R)File 149:TGG Health&Wellness DB(SM)  
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01771888 SUPPLIER NUMBER: 20767030 (USE FORMAT 7 OR 9 FOR FULL TEXT)  
**Atrial Flutter : Advances in Mechanism and Management. (book reviews**  
Markowitz, Steven M.  
Chest, v113, n5, pA16(1)  
May,  
1998

DOCUMENT TYPE: Review PUBLICATION FORMAT: Magazine/Journal; Refereed  
ISSN: 0012-3692 LANGUAGE: English RECORD TYPE: Fulltext  
TARGET AUDIENCE: Professional REVIEW GRADE: B  
WORD COUNT: 461 LINE COUNT: 00042

**Atrial Flutter : Advances in Mechanism and Management...**

The past 2 decades have witnessed considerable progress in the study of **atrial arrhythmogenesis**; **atrial flutter**, in particular, has emerged as the most completely described **arrhythmia** of this class. Animal models of **atrial flutter** and studies in humans have elucidated broad electrophysiologic principles and expanded our understanding of the reentrant process. This knowledge, in turn, has enabled the development of effective treatment targeted at **atrial flutter** as well as other reentrant **arrhythmias**. In preparing a comprehensive textbook devoted to the mechanisms and management of **atrial flutter**, Albert Waldo and Paul Touboul have provided us with an important review, appropriate both for basic scientists and for clinicians.

The book begins with sections devoted to **atrial** anatomy and the physiologic determinants of reentry. Collectively, these elegantly written chapters (including discussions by...

...principles of reentrant excitation. These are followed by chapters describing four important animal models of **atrial flutter** (those developed by Penelope Boyden, Lawrence Frame, Albert Waldo, and **Gregory**

Feld ). In reviewing these experimental data, the authors not only explore the pathophysiology of **atrial flutter** but also provide insights into the nature of the reentrant process and explain fundamental concepts. The section devoted to **atrial flutter** in humans includes a lucid discussion of entrainment (by Albert Waldo) and several chapters which...

...of the autonomic nervous system from the basic and clinical perspectives.

The therapeutic aspects of **atrial flutter** are addressed in sections devoted to drug treatment, electrical therapy, and ablation techniques. In the...

...and the role of rate control. The various electrical modalities reviewed in this book include **atrial** pacing and electric **cardioversion**, with a chapter that addresses the role of the implantable **atrial** defibrillator. Finally, catheter and surgical techniques of ablation are described by those who have pioneered...

...Overall, this text is a useful compilation of essays organized around the central theme of **atrial flutter**. These discussions have broad applicability beyond the scope of **atrial flutter** and provide a thorough review of reentrant **arrhythmogenesis**.

---

4/3,K/14 (Item 4 from file: 149)  
DIALOG(R)File 149:TGG Health&Wellness DB(SM)  
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01302250 SUPPLIER NUMBER: 10840813 (USE FORMAT 7 OR 9 FOR FULL TEXT)  
By how much does dietary salt reduction lower blood pressure? III. Analysis of data from trials of salt reduction.

Law, M.R. ; Frost, C.D.; Wald, N.J  
British Medical Journal, v302, n6780, p819(6)  
April 6,  
1991

PUBLICATION FORMAT: Magazine/Journal ISSN: 0959-8146 LANGUAGE: English  
RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE: Professional  
WORD COUNT: 3643 LINE COUNT: 00404

Law, M.R. ...  
... WVR, O'Connor DT. Sympathetic nervous system activity during sodium restriction in essential hypertension. Clin **Cardiol** 1980;3:348-51.

[18] Priddle WW. Hypertension--sodium and potassium studies. Can Med Assoc...J Aust 1981;ii:396-7.

[52] Koga Y, Gillum RF, Kubicek WG. An impedance **cardiographic** study of the mechanism of blood pressure fall after moderate dietary sodium restriction. Jpn Heart...

...8.

[81] Bucknall CA, Morris GK, Mitchell JRA. Physicians' attitudes to four common problems: hypertension, **atrial fibrillation**, transient ischaemic attacks and angina pectoris. BMJ 1986;293:739-42.

[82] James WPT, Ralph...

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4/3,K/15 (Item 1 from file: 441)  
DIALOG(R)File 441:ESPICOM Pharm&Med DEVICE NEWS  
(c) 2004 ESPICOM Bus.Intell. All rts. reserv.

00060312 00064071 (USE FORMAT 7 OR 9 FOR FULLTEXT)

**Boston Scientific gains FDA clearance for the EPT-1000 XP cardiac ablation system**

Medical Industry Week  
28 August 2003 (20030828)  
RECORD TYPE: FULLTEXT WORD COUNT: 261

COMPANY: Boston Scientific

(THIS IS THE FULLTEXT)

**Boston Scientific gains FDA clearance for the EPT-1000 XP cardiac ablation system**

TEXT:

Boston Scientific has received premarket approval from the FDA for its EPT-1000 XP **cardiac** ablation system for the treatment of **atrial flutter**. Dr Gregory Feld, Professor of Medicine, Director of the Electrophysiology Program at the University of California San Diego... ..energy), resulting in shorter procedure times with fewer ablations and a chronic success rate for **atrial flutter** in excess of 96 per cent. **Atrial flutter** is caused by abnormal electrical signal in the right **atrium**, in a circular pattern. A successful ablation procedure occurs when a linear lesion is created...

...directional manner, allowing the heart to return to normal rhythm permanently. The EPT-1000 XP **cardiac** ablation system allows for 8 and 10mm tip electrodes to be used with up to 100 watts of radiofrequency energy to treat **atrial flutter**. The company says this level of energy has demonstrated excellent results when compared with 50...

...persisted through the six-month measurement period. They also displayed a marked reduction in both **arrhythmia**-related symptoms and the use of medications to treat the condition.

---

4/3,K/16 (Item 2 from file: 441)

DIALOG(R)File 441:ESPICOM Pharm&Med DEVICE NEWS  
(c) 2004 ESPICOM Bus.Intell. All rts. reserv.

00044561 00046841 (USE FORMAT 7 OR 9 FOR FULLTEXT)

**Boston Scientific provides EPT-1000 XP Cardiac Ablation System update**

Medical Industry Week  
13 August 2002 (20020813)  
RECORD TYPE: FULLTEXT WORD COUNT: 435

COMPANY: Boston Scientific; EP Technologies

(THIS IS THE FULLTEXT)

**Boston Scientific provides EPT-1000 XP Cardiac Ablation System update**

TEXT:

...submitted six of the seven PMA modules to the FDA for its EPT-1000 XP **cardiac** ablation system for the treatment of **atrial flutter**. The six modules submitted have been reviewed, accepted and closed by the FDA. The seventh...

...for a PMA, which would allow product commercialisation in the US. The EPT-1000 XP **cardiac** ablation system uses radiofrequency (RF) to treat **atrial flutter** by creating a linear lesion across the tricuspid isthmus, interrupting the abnormal electrical circuit causing the **atrial flutter** and allowing the heart to return to normal rhythm. Patients with **atrial flutter** have been treated using a variety of methods such as electrical **cardioversion** and anti-**arrhythmic** drugs. However, these approaches are palliative and the **arrhythmia** may require alternative treatment. RF **cardiac** ablation offers a viable alternative to these palliative treatments, the company stated.

The Boston Scientific **atrial flutter** system consists of a range of Blazer II XP bi-directional, temperature-controlled **cardiac** ablation catheters and the EPT-1000 XP generator. While the new EPT-1000 XP generator is essentially the same as the currently available EPT-1000 generator installed in US **cardiac** ablation centres, the forthcoming version will increase the available RF power level from 50W to 100W. Dr **Gregory Feld**, Professor of Medicine, Director of the Electrophysiology Program at the University of California San Diego Medical Center and Principal Investigator of Boston Scientific's **atrial flutter** study, said that treating **atrial flutter** using a 10mm tip catheter, such as the Blazer II XP, has demonstrated a definite...

...dramatic" improvement in their quality of life after being treated with the EPT-1000 XP **cardiac** ablation system.

According to Tom Coen, President of the EP Technologies, a division of Boston...

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4/3,K/17 (Item 3 from file: 441)

DIALOG(R)File 441:ESPICOM Pharm&Med DEVICE NEWS

(c) 2004 ESPICOM Bus.Intell. All rts. reserv.

00010051 00011460 (USE FORMAT 7 OR 9 FOR FULLTEXT)

**Fidus reports microwave ablation continues to successfully cure arrhythmia**

Medical Device Companies Analysis

15 September 1997 (19970915)

RECORD TYPE: FULLTEXT WORD COUNT: 204

COMPANY: Hopital de Sacre-Coeur de Montreal; Fidus Medical Technology Corporation

(THIS IS THE FULLTEXT)

**Fidus reports microwave ablation continues to successfully cure arrhythmia**

TEXT:

...has reported that Fidus Medical Technology Corporation's microwave catheter ablation system continues to cure **atrial flutter**. Fidus is conducting an international multisite programme to produce linear lesions aimed at developing a cure for **atrial fibrillation**. Dr. Molin's most recent procedure used a microwave catheter ablation system which delivered controlled...

...linear lesions, Dr. Molin created a lesion across the IVC-TV Isthmus within the right **atrium** of his patient's heart. This lesion interrupts the abnormal electrical circuit which is the cause of **atrial flutter**. Dr. Molin remarked that "the procedure took less time than normally

experienced with RF. After...

...line block was created in the isthmus." The total procedure time was approximately one hour.

**Ted Ormsby**, Vice President of R&D and Technology at Fidus, stated that "this is a continuous validation in the use of a catheterised microwave ablation system for the successful treatment of **atrial flutter** and **fibrillation**. In cases where microwave has been used, we clearly see a competitive advantage over RF...

---

4/3,K/18 (Item 4 from file: 441)

DIALOG(R)File 441:ESPICOM Pharm&Med DEVICE NEWS

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00007976 00001090 (USE FORMAT 7 OR 9 FOR FULLTEXT)

**Microwave ablation contributes to successful treatment of atrial flutter**

Medical Device Companies Analysis

12 May 1997 (19970512)

RECORD TYPE: FULLTEXT WORD COUNT: 184

COMPANY: Fidus Medical Technology Corporation

(THIS IS THE FULLTEXT)

**Microwave ablation contributes to successful treatment of atrial flutter**

TEXT:

...reported that its microwave catheter ablation system has been used successfully in the treatment of **atrial flutter**.

Dr. Franck Molin of Hopital de Sacre Coeur de Montreal, Montreal, Canada reported this therapeutic breakthrough in an ablation procedure to cure **atrial flutter**. The procedure used a catheter system which delivered controlled microwave energy to carefully targeted tissue...

...long linear lesions, Dr. Molin created a lesion across the targeted tissue within the right **atrium** of his patient's heart.

After the creation of the primary lesion with the experimental...

...complete the lesion. This lesion interdicted the abnormal electrical circuit which is the cause of **atrial flutter**.

**Ted Ormsby**, Vice President of Engineering at Fidus, who assisted in the procedure, stated that this advance is another milestone in the continuous development of microwave catheters to treat **atrial flutter** and **atrial fibrillation**. Clinical studies are being conducted in North America and Europe to further evaluate and improve...

---

4/3,K/19 (Item 1 from file: 621)

DIALOG(R)File 621:Gale Group New Prod.Annou.(R)

(c) 2004 The Gale Group. All rts. reserv.

02225059 Supplier Number: 57395502 (USE FORMAT 7 FOR FULLTEXT)

**New Findings Indicate Potential Efficacy of Cryoablation in Treating Irregular Heartbeat.**

Business Wire, p0444

Nov 8, 1999

Language: English Record Type: Fulltext

Document Type: Newswire; Trade

Word Count: 583

... lesions in the heart wall, may offer physicians promise in correcting certain electrical conduction disorders ( **arrhythmias** ) in the heart. **Arrhythmias** that cause rapid heartbeats, such as ventricular **tachycardia** (VT), diminish the heart's pumping efficiency and may cause patients to feel lightheaded, experience palpitations, or even faint. These **arrhythmias** are often lethal and more than 250,000 new cases are diagnosed in the U...

...the transcatheter cryoablation study, which was led by University of California San Diego (UCSD) physician **Gregory K. Feld**, M.D., professor of medicine and director of the **cardiac** electrophysiology programs, was to establish the safety and efficacy of cryoablation in animal studies. Currently...

...by this technology may not penetrate deep enough into the heart tissue to cure the **arrhythmia**. Additionally, the heat caused by the RF procedure can cause tissue charring and clotting. These...

...look forward to future investigation of this procedure and its potential benefits for patients with **cardiac arrhythmias**."

Transcatheter cryoablation findings indicate that physicians using this technology can correct electrical conduction disorders by...

...medical device company focused on the introduction of a novel cryoablation technology for gynecology and **cardiology**. CryoGen has developed a miniature, closed-cycle cryoablation device and supporting system that enables physicians...

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Set	Items	Description
S1	176586	ABLAT? OR CRYOABLAT? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR MICROWAV? OR MICRO() (WAVE? OR WAVING) OR ELECTROSURG? - OR ELECTRO?(2N)SURG? OR ELECTRICAL?()ISOLAT?
S2	58971	ATRIA? OR ATRIU? OR VENTRI? OR CARDI? OR ISTHMUS? OR INTRA- ATRI? OR INTRAVENTR? OR TRANSATRI? OR TRANSVENTR? OR MITRA?(3- N)VALV?
S3	16186	FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUT- TER? OR (IRREGULAR? OR RAPID?) () (HEARTBEAT? OR HEART()BEAT?)
S4	904506	CATHETER? OR CANULA? OR CANNULA? OR CANNULLA? OR CANULLA? - OR LUMEN? OR TUBE? OR TUBING?
S5	196601	ANTENNA? OR (COAXIAL? OR CO()AXIAL?) ()CABL? OR GUIDEWIR? OR GUIDE() (WIRE? OR WIRING)
S6	712443	USHAP? OR U()SHAP? OR CURV? OR LOOP? OR (180 OR ONE()HUNDR- ED(2N)EIGHTY) ()DEGREE? OR UTURN? OR U()TURN? OR (HAIRPIN? OR - HAIR()PIN) ()TURN?
S7	31996	PRESHAP? OR PRE()SHAP? OR MEMORY()METAL? OR NITINOL? OR MA- RTEN? OR AUSTEN?
S8	1830309	LINE OR LINES OR LINED OR LINEAR? OR LESION? OR CURVILINE? OR SCORE? OR SCORING? OR SCAR? OR ULCER? OR SCORIF?
S9	4244843	METHOD? ?
S10	3089810	SYSTEM?
S11	2486572	PROCESS??
S12	203811	PROCEDUR?
S13	226922	TECHNIQUE?
S14	248095	IC=A61B?
S15	329	S1 AND S2 AND S3 AND S4
S16	262	S15 AND S14
S17	329	S15:S16
S18	2	S17 AND S6:S7(10N)S5
S19	22	S17 AND S8 AND S5
S20	4	S19 AND S6:S7
S21	24	S18:S20
S22	24	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 347:JAPIO Nov 1976-2004/May(Updated 040903)

(c) 2004 JPO & JAPIO

File 350:Derwent WPIX 1963-2004/UD,UM &UP=200459

(c) 2004 Thomson Derwent

?

22/3,K/1 (Item 1 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

*SOME OF THE  
INVENTORS*

016339737 \*\*Image available\*\*  
WPI Acc No: 2004-497634/200447  
Related WPI Acc No: 2000-532552; 2004-118192  
XRPX Acc No: N04-392908

**Biological tissue ablating method for body vessel e.g. atrium ,  
involves sensing reflected and forward RF energy pulses and adjusting  
output frequency of RF pulses to match transmission line impedance  
with load impedance**

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I)

Inventor: LAW M; LEUNG G L; ORMSBY T C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20040106917	A1	20040603	US 98211188	A	19981214	200447 B
			US 99459058	A	19991211	
			US 2002306757	A	20021127	
			US 2003637325	A	20030808	

Priority Applications (No Type Date): US 2003637325 A 20030808; US 98211188  
A 19981214; US 99459058 A 19991211; US 2002306757 A 20021127

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20040106917	A1	11	A61B-018/18	CIP of application US 98211188 CIP of application US 99459058 CIP of application US 2002306757 CIP of patent US 6190382 CIP of patent US 6663625

**Biological tissue ablating method for body vessel e.g. atrium ,  
involves sensing reflected and forward RF energy pulses and adjusting  
output frequency of RF pulses to match transmission line impedance  
with load impedance**

Abstract (Basic):

... The method involves generating a train of **radio frequency** (**RF**) energy pulses at an output frequency by an **RF** signal oscillator (330) to transmit in a transmission line (342) to an **RF antenna** (343). Reflected and forward signals of the **RF** pulses are sensed when the **antenna** is placed adjacent to a biological tissue. The output frequency of the **RF** pulses is adjusted to match the transmission line impedance with load impedance.

... An INDEPENDENT CLAIM is also included for a system for biological tissue **ablation**.

...Used for **ablating** a biological tissue (claimed) and occlusion of a body vessel e.g. an **atrium** of a patient and liquid-filled **lumens** of animals such as heart, liver and vessels of a human for the treatment of **cardiac arrhythmia** and solid tumor...

...The method adjusts the output frequency of the **RF** energy pulses to provide the impedance match between the **antenna** and the biological tissue load, thereby minimizing **RF** energy reflection. The minimized **RF** energy reflection reduces local heating of the **antenna** and hence the method avoids unwanted **ablation** affects...

...The drawing shows a schematic block diagram of a **radio frequency** based **catheter** system...



... RF based **catheter** system (300...

... RF signal oscillator (330...

... RF transmission **line** (342...

... RF **antenna** (343

...Title Terms: **ABLATE** ;

International Patent Class (Main): **A61B-018/18**

22/3,K/2 (Item 2 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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016260011 \*\*Image available\*\*

WPI Acc No: 2004-417905/200439

Related WPI Acc No: 2000-595734; 2001-417353; 2003-016255; 2004-118915;  
2004-327142

XRAM Acc No: C04-156962

XRPX Acc No: N04-331545

Catheter assembly for treatment of cardiac arrhythmia comprises  
catheter body including distal portion forming coil, lumen extending  
from proximal to distal portion and ablation section formed along coil  
and defining loop

Patent Assignee: MEDTRONIC INC (MEDT )

Inventor: SKARDA J R; STEWART M T

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20040082948	A1	20040429	US 99286048	A	19990405	200439 B
			US 2000733356	A	20001208	
			US 2003689112	A	20031020	

Priority Applications (No Type Date): US 2000733356 A 20001208; US 99286048  
A 19990405; US 2003689112 A 20031020

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20040082948	A1	48	A61B-018/14	CIP of application US 99286048 Div ex application US 2000733356 CIP of patent US 6325797

Catheter assembly for treatment of cardiac arrhythmia comprises  
catheter body including distal portion forming coil, lumen extending  
from proximal to distal portion and ablation section formed along coil  
and defining loop

Abstract (Basic):

... A catheter assembly comprises a catheter body including a  
first lumen extending from proximal to distal portion; and an  
ablation section formed along the coil formed by distal portion and  
defining a loop transverse to the longitudinal axis defined by  
intermediate portion. The ablation section comprises a microporous  
material in fluid communication with the first lumen to irrigate  
fluid from the lumen to an exterior surface of the section.

... A catheter assembly comprises a catheter body (222)  
including a proximal portion; an intermediate portion extending from  
the proximal portion and...

...a distal portion (232) extending from the intermediate portion and  
forming a helix; a first lumen extending from the proximal portion to  
the distal portion; and an ablation section formed along the coil and  
defining a loop (234) transverse to the longitudinal axis. The  
ablation section is formed of a microporous material in fluid  
communication with the first lumen to irrigate fluid from the first  
lumen to an exterior surface of the ablation section. At least one  
electrode is associated with the ablation section. A fluid source  
supplies a liquid to the first lumen. Upon activation, the electrode  
supplies an ablation energy to fluid irrigated to the exterior  
surface of the ablation section for ablating a continuous, closed  
lesion pattern...

...An INDEPENDENT CLAIM is also included for a method for forming an

ablation pattern to electrically isolate a vessel from a chamber, wherein the vessel has an ostium formed at a chamber wall, for treatment of cardiac arrhythmia by selecting a catheter assembly including a catheter body, a first shaping wire and electrode(s); guiding the distal portion including an ablation section into the chamber; forming the distal portion to a helical configuration with the distal segment of the shaping wire such that the ablation section forms a loop; directing the distal portion such that the ablation section contacts the chamber wall about the vessel ostium; and energizing the electrode to ablate a continuous, closed lesion pattern about the vessel ostium to electrically isolate the vessel from the chamber...

...For treatment of cardiac arrhythmia (claimed...

...The catheter assembly of the invention provides a highly viable tool for electrically isolating a vessel, e.g. pulmonary vein or coronary sinus, from a chamber, e.g. left atrium.

...The figure shows a side view of a portion of a catheter assembly in a deployed position...

... Catheter body (222...

... Loop (234...

... Loop axis (C8

Technology Focus:

... Preferred Materials: The ablation section is formed of a microporous polymer, preferably high-density, expanded Polytetrafluoroethylene (RTM; PTFE...

...Preferred Components: The ablation section has a straightened length of 2-8 inches. The electrode is disposed within the first lumen at the ablation section. It includes a coil electrode. The electrode has a length approximating or slightly greater than a length of the ablation section. The loop defines a loop axis (C8). The loop axis and the longitudinal axis are parallel. A shaping wire is coaxially maintained by the catheter body. It includes a proximal segment and a distal segment. The distal segment is formed...

...the distal portion as a helix. The shaping wire is slidably disposed within the first lumen. The catheter body further includes a second lumen extending from the proximal portion to the distal portion. The shaping wire is slidably disposed within the second lumen. A guide catheter forming a lumen sized to slidably receive the catheter body and terminating at an opening is movable between a retracted position in which the...

...opening and a deployed position in which the distal portion is distal the opening. A guide wire is coaxially maintained by the catheter body. It is selectively movable relative to the catheter body. It includes a proximal section and a distal section. In a deployed position, the distal section of the guide wire is concentric with and extends distally beyond the helix formed at the distal portion of the catheter body. A sensing electrode is positioned along the helix distal or proximate the ablation section for sensing tissue conductivity. The loop is axially compressible to an axially

compressed position following contact with a tissue wall. The **loop** is configured to be planar in the axially compressed position. The **loop** may be axially compressible to an axially compressed position following contact with a tissue wall and further configured to be non-planar in the axially compressed position. The **loop** is configured to have a saddle shape in the axially compressed position. A delivery **catheter** having a distal locator forms a **catheter** body **lumen** terminating at an opening proximal the distal locator. The **catheter** body is slidably disposed within the **catheter** body **lumen** such that the **catheter** body is selectively deployable and retractable relative to the distal locator via the opening. The delivery **catheter** is configured to be selectively bendable distal the opening. It includes a steering device for...

Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-018/14**

22/3,K/3 (Item 3 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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016169461 \*\*Image available\*\*  
WPI Acc No: 2004-327348/200430  
XRPX Acc No: N04-261070

Cardiac chamber isolation method for cardiac arrhythmias treatment,  
involves anchoring optical assembly introduced at pulmonary vein  
proximate ostium, and conducting laser light in path from assembly to  
ablation region

Patent Assignee: BIOSENSE INC (BIOS-N); BEN-HAIM S (BENH-I); GOVARI A  
(GOVA-I); LEATHAM M (LEAT-I); SCHWARTZ Y (SCHW-I); YARON U (YARO-I)

Inventor: BEN-HAIM S; GOVARI A; LEATHAM M; SCHWARTZ Y; YARON U

Number of Countries: 036 Number of Patents: 006

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20040054360	A1	20040318	US 2002245613	A	20020917	200430 B
CA 2440495	A1	20040317	CA 2440495	A	20030911	200430
EP 1400215	A1	20040324	EP 2003255782	A	20030916	200430
JP 2004105735	A	20040408	JP 2003323394	A	20030916	200430
KR 2004025612	A	20040324	KR 200364479	A	20030917	200446
AU 2003246062	A1	20040401	AU 2003246062	A	20030912	200453

Priority Applications (No Type Date): US 2002245613 A 20020917

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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US 20040054360	A1		12	A61B-018/18	
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CA 2440495	A1	E		A61B-018/20	
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EP 1400215	A1	E		A61B-018/24	
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Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB

GR HU IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR

JP 2004105735	A		16	A61B-018/20	
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KR 2004025612	A			A61B-018/24	
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AU 2003246062	A1			A61B-018/08	
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Cardiac chamber isolation method for cardiac arrhythmias treatment,  
involves anchoring optical assembly introduced at pulmonary vein  
proximate ostium, and conducting laser light in path from assembly to  
ablation region

Abstract (Basic):

... energy is thereafter conducted in a path extending from the  
optical assembly to a circumferential ablation region of the vein.  
... An INDEPENDENT CLAIM is included for cardiac chamber isolating  
apparatus...

...For treating cardiac arrhythmias by ablating in vicinity of  
pulmonary venous tissue...

...Provides improved method for electrically isolating the pulmonary  
vein by accomplishing circumferential conduction block surrounding the  
vein ostium in a single ablation application of laser light energy. A  
circumferential ablation lesion is produced around the ostium,  
which effectively blocks electrical propagation between the vein and  
the left atrium .  
...

...The figure shows a therapeutic catheter that is constructed and  
operative in accordance with the method...

...intravascular catheter (10...

...coaxial guide wire lumen (24

Title Terms: CARDIAC ;

International Patent Class (Main): A61B-018/08 ...

... A61B-018/18 ...

... A61B-018/20 ...

... A61B-018/24

International Patent Class (Additional): A61B-018/22 ...

22/3,K/4 (Item 4 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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*Some of the  
inventions*

015960351 \*\*Image available\*\*  
WPI Acc No: 2004-118192/200412  
Related WPI Acc No: 2000-532552; 2004-497634  
XRPX Acc No: N04-094382

**Body tissue ablation method involves deploying radio frequency antenna out of catheter at target ablation site, by sliding hollow cable over monorail guide**

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I)

Inventor: LAW M; LEUNG G L; ORMSBY T C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6663625	B1	20031216	US 98211188	A	19981214	200412 B
			US 99459058	A	19991211	

Priority Applications (No Type Date): US 99459058 A 19991211; US 98211188 A 19981214

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 6663625	B1	18	A61B-018/18	CIP of application US 98211188
				CIP of patent US 6190382

**Body tissue ablation method involves deploying radio frequency antenna out of catheter at target ablation site, by sliding hollow cable over monorail guide**

Abstract (Basic):

... electrically conductive inner and outer conductors, is included in an electrical hollow cable that connects **radio frequency (RF)** energy source and **RF antenna (54)** mounted over a monorail (36). The **antenna** is deployed out of the **catheter (3)** at the targeted **ablation site**, by sliding the cable over a monorail guide.

... For **ablating** biological tissue within body vessel of patient, for treatment of **cardiac arrhythmias**.

...By using a simple and reliable technique, the **catheter** electrode is placed at required **ablation** site at high precision, thereby objective of maze procedure in achieving lineal **lesion** without need of open heart surgery is realized...

...The figure shows a partial sectional view of the distal portion of **RF catheter ablation** system...

... **catheter (3)**...

... **catheter lumen (16)**...

... **RF antenna (54)**

...Title Terms: **ABLATE** ;

International Patent Class (Main): **A61B-018/18**

22/3,K/5 (Item 5 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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015293689 \*\*Image available\*\*  
WPI Acc No: 2003-354623/200333  
XRAM Acc No: C03-093523  
XRPX Acc No: N03-283322

Ablation of cardiac tissue, for treating e.g. atrial fibrillation  
, involves exposing cardiac tissue to ionizing radiation, to form  
lines of ablation or lesion on cardiac tissue  
Patent Assignee: NOVOSTE CORP (NOVO-N); BONAN R (BONA-I); GRIFFIS J C  
(GRIF-I); LARSEN C E (LARS-I); LEROHL A L (LERO-I); SCHUMER D B (SCHU-I);  
TRIP R (TRIP-I)  
Inventor: BONAN R; GRIFFIS J C; LARSEN C E; LEROHL A L; SCHUMER D B; TRIP R  
Number of Countries: 102 Number of Patents: 003  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200326480	A2	20030403	WO 2002US30159	A	20020923	200333 B
US 20030153802	A1	20030814	US 2001324299	P	20010924	200355
			US 2002252731	A	20020923	
EP 1429649	A2	20040623	EP 2002768885	A	20020923	200441
			WO 2002US30159	A	20020923	

Priority Applications (No Type Date): US 2001324299 P 20010924; US  
2002252731 A 20020923

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
WO 200326480	A2 E	64	A61B-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU  
ZA ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB  
GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW  
US 20030153802 A1 A61N-001/00 Provisional application US 2001324299

EP 1429649 A2 E A61B-001/00 Based on patent WO 200326480  
Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR  
Ablation of cardiac tissue, for treating e.g. atrial fibrillation  
, involves exposing cardiac tissue to ionizing radiation, to form  
lines of ablation or lesion on cardiac tissue

Abstract (Basic):

... A cardiac tissue is ablated, by exposing it to ionizing  
radiation from an ionizing radiation source near to or in contact with  
the cardiac tissue.

... An INDEPENDENT CLAIM is also included for an apparatus for  
treating cardiac tissue, comprising an elongated catheter (30) with  
a passageway extending between two end portions, for receiving an  
ionizing radiation source...

...For ablating cardiac tissue to treat atrial fibrillation or  
pulmonary vein stenosis (claimed), or other electrophysiological  
problems with the heart, such as cardiac arrhythmias.

...The novel method allows the catheter to be accurately placed within

11 good

See  
drawings +  
claims in  
"US  
version"

[24 SEPT 2001 PROV.]



the heart, inside the **atrium** (4) particularly in the pulmonary veins, before the radioactive sources are introduced into the **catheter**, thus minimizing unnecessary radiation exposure; creating **linear lines** of **ablation** at desired locations; permitting repositioning of the **catheter** while the radioactive sources are outside the patient's body; and reducing the treatment time...

...be employed to modify the conduction characteristics of the AV node to treat or prevent **arrhythmias** without complete **ablation**.

...The figure shows a **catheter** inserted into the right **atrium** along the pre-formed **guide wire**.

... **Atrium** (4...

... **Catheter** (30...

... **Guide wire** (58

Technology Focus:

... is held by a fixation device in immediate proximity to or in contact with the **cardiac** tissue to be **ablated**. The distal end portion of the **catheter** is in immediate proximity or contact with **cardiac** tissue to be **ablated** and advancing the ionizing radiation source through the **catheter** to a location adjacent to the **cardiac** tissue to be **ablated**. A **line** of **ablated** tissue is formed, which isolates a pulmonary vein(s) from the remaining portion of the left **atrium**. The method also involves cooling the **cardiac** tissue to identify the tissue to be **ablated**; sensing an electrophysiological characteristic of the **cardiac** tissue; advancing the distal end of the **catheter** along a **guide wire** (58) to the **cardiac** tissue; and steering the distal end portion of the **catheter** to the **cardiac** tissue. The conduction characteristics of the atrioventricular (AV) node are modified to treat reentrant **tachycardia**.

...radiation source is an elongated and continuous beta radiation source, preferably a beta emitter. The **catheter** includes at least two-spaced apart electrode (61) for sensing the electrophysiological characteristics of the **cardiac** tissue. The radiation source includes individual radiation sources in a **line**, to define the elongated source, which is advanced along the **catheter** by fluid pressure. The **catheter** is inserted through the **atrial** septum. The distal end of the **catheter** conforms to the shape of a **guide wire**. The pre-formed shape is spiral. The **catheter** is held by a fixation device. It includes an inflation **lumen** extending between the end portions. The actuated control mechanism comprises a steering wire(s) extending through the **catheter** between the two ends. The fixation device includes retractable and expandable ribs, inflatable member, or a balloon at the distal end portion and communicating with the inflation **lumen**. It includes suction ports for attachment to a **cardiac** surface, or anchors to engage a **cardial** surface and hold the distal end portion. The balloon extends less than 360degrees around the **catheter** shaft.

Title Terms: **ABLATE** ;

International Patent Class (Main): **A61B-000/00** ...

... **A61B-001/00**

22/3,K/6 (Item 6 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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014878001 \*\*Image available\*\*

WPI Acc No: 2002-698707/200275

Related WPI Acc No: 1999-444508; 1999-560910; 1999-571979; 2000-097867;  
2000-106224; 2000-374497; 2001-069880; 2001-168765; 2001-327451;  
2001-366335; 2001-367086; 2001-396796; 2001-424434; 2001-424986;  
2001-475461; 2001-513992; 2001-513993; 2001-528497; 2001-541213;  
2001-541846; 2001-607348; 2001-638598; 2002-010846; 2002-017541;  
2002-026554; 2002-089577; 2002-130712; 2002-204303; 2002-381127;  
2002-392970; 2002-433895; 2002-433896; 2002-470768; 2002-619098;  
2002-681741; 2003-103306; 2003-276174; 2003-278507; 2003-312710;  
2003-333533; 2003-421016; 2003-503202; 2003-645703; 2003-776583;  
2004-346625; 2004-561429

XRAM Acc No: C02-197900

XRPX Acc No: N02-550944

Device for treating atrial fibrillation and restenosis in tissue,  
comprises ablation catheter, introducer sheath for ablation  
catheter, heater disposed adjacent or within sheath and control unit for  
heater

Patent Assignee: INNERCOOL THERAPIES INC (INNE-N); DOBAK J D (DOBA-I);  
INDERBITZEN R S (INDE-I); KRAMER H W (KRAM-I); YON S A (YONS-I); COOPER S  
R (COOP-I); MAGERS M (MAGE-I)

Inventor: COOPER S R; DOBAK J D; INDERBITZEN R S; KRAMER H W; YON S A;  
MAGERS M

Number of Countries: 100 Number of Patents: 005

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200269862	A1	20020912	WO 2002US6349	A	20020301	200275 B
US 20020156469	A1	20021024	US 9852545	A	19980331	200277
			US 98215038	A	19981216	
			US 2000516319	A	20000301	
			US 2001272550	P	20010301	
			US 2001273095	P	20010302	
			US 2001787599	A	20010321	
			US 200286585	A	20020228	
US 20030014095	A1	20030116	US 2001273095	P	20010302	200308
			US 2001787599	A	20010321	
			US 2002200028	A	20020718	
US 20030125721	A1	20030703	WO 2002US6349	A	20020301	200345
			US 2002110360	A	20021029	
AU 2002255643	A1	20020919	AU 2002255643	A	20020301	200433

Priority Applications (No Type Date): US 200286585 A 20020228; US  
2001272550 P 20010301; US 2001273095 P 20010302; US 2001787599 A 20010321  
; US 9852545 A 19980331; US 98215038 A 19981216; US 2000516319 A 20000301  
; US 2002200028 A 20020718; US 2002110360 A 20021029

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200269862 A1 E 78 A61F-007/00

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU  
ZA ZM ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR  
IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZM ZW

US 20020156469 A1 A61B-018/02 CIP of application US 9852545  
CIP of application US 98215038

CIP of application US 2000516319  
 Provisional application US 2001272550  
 Provisional application US 2001273095  
 CIP of application US 2001787599  
 CIP of patent US 6231595  
 CIP of patent US 6261312  
 US 20030014095 A1            A61F-007/00    Provisional application US 2001273095  
 CIP of application US 2001787599.  
 US 20030125721 A1            A61B-018/02  
 AU 2002255643 A1            A61F-007/00    Based on patent WO 200269862

Device for treating atrial fibrillation and restenosis in tissue,  
 comprises ablation catheter , introducer sheath for ablation  
 catheter , heater disposed adjacent or within sheath and control unit for  
 heater

Abstract (Basic):

- ... Providing an enhanced method and device to treat atrial fibrillation or to inhibit or reduce the rate of restenosis following angioplasty or stent placement.
- ... A device for treating tissue, comprises an ablation catheter (100), an introducer sheath for the ablation catheter , the introducer sheath, a heater disposed adjacent or within the introducer sheath and a control...
- ...1) a method of treating atrial fibrillation while preventing tissue damage to the atrial septum, which involves inserting a trocar wire capable of rupturing the atrial septum from the femoral vein into the right atrium , forming a hole using the trocar wire in the atrial septum between the right and left atrium , inserting an introducer sheath into the hole, which partially contacts the atrial septum, inserting a guide wire through the sheath into the right and left atrium and further into a pulmonary vein, disposing ablation catheter over the guidewire into a volume defined by a joint of the left atrium and the pulmonary vein, flowing a cryofluid into a balloon disposed within the ablation catheter to ablate tissue adjacent the joint of the left atrium and the pulmonary vein, and operating and controlling a heater disposed adjacent or within the introducer sheath. The heater is thermally coupled to the atrial septum...
- ...3) a method for reducing atrial fibrillation which involves inserting a catheter having cold balloon and inflating the balloon with working fluid having a temperature of -10...
- ...Useful for treating reducing atrial fibrillation , restenosis after angioplasty in a blood vessel...
- ...The figure shows a side schematic view of a catheter .
- ... Catheter (100...
- ...Supply lumen (120
- Technology Focus:
- ... Preferred Arrangement: The heater has an inlet tube (128) fluidically coupled to interior of the introducer, outlet orifice(s) disposed in the introducer...
- ...The resistive heater is helically wound on the sleeve. The device is an ablation catheter containing a guidewire lumen , a supply lumen

(120), and a return lumen .

...

...The guidewire lumen extends from a proximal end (130) to a distal end of the catheter .

...

...Marker band(s) are disposed on the catheter to locate a working region of the device...

...The device further comprises cryofluid source having a supply tube and a return tube , coupled to supply lumen and the return tube coupled to the return lumen .

...

...controlled by a power to a resistive heater by flowing a warming fluid into inlet tube and flowing the warming fluid out of outlet orifice disposed in the introducer sheath, or...

...The cardiac surgical procedure includes valve replacement...

...The presence of dissolved gases is sensed during the circulating with an in- line gas sensor

...Title Terms: ATRIUM ;

International Patent Class (Main): A61B-018/02 ...

International Patent Class (Additional): A61B-018/04

22/3,K/7 (Item 7 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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014326802 \*\*Image available\*\*  
WPI Acc No: 2002-147505/200219  
XRPX Acc No: N02-111865

**Deflectable tip catheter for positioning deflectable tip catheter in pulmonary vein ostium has deflectable tip located along distal end portion and ablation element disposed on distal end portion**

Patent Assignee: ATRIONIX INC (ATRI-N); LESH M D (LESH-I); PEAKCOCK J C (PEAK-I); ROSS M R (ROSS-I); TAYLOR K J (TAYL-I)

Inventor: LESH M D; PEAKCOCK J C; ROSS M R; TAYLOR K J

Number of Countries: 095 Number of Patents: 005

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200187174	A1	20011122	WO 2001US15947	A	20010516	200219 B
AU 200163221	A	20011126	AU 200163221	A	20010516	200222
US 20020165535	A1	20021107	US 2000205009	P	20000516	200275
			US 2001858523	A	20010516	
EP 1286624	A1	20030305	EP 2001937490	A	20010516	200319
			WO 2001US15947	A	20010516	
JP 2003533268	W	20031111	JP 2001583645	A	20010516	200375
			WO 2001US15947	A	20010516	

Priority Applications (No Type Date): US 2000205009 P 20000516; US 2001858523 A 20010516

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200187174	A1	E 114	A61B-018/14		
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Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

AU 200163221	A		A61B-018/14	Based on patent WO 200187174
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US 20020165535	A1		A61B-018/14	Provisional application US 2000205009
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EP 1286624	A1	E	A61B-018/14	Based on patent WO 200187174
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Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR

JP 2003533268	W	125	A61M-025/01	Based on patent WO 200187174
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**Deflectable tip catheter for positioning deflectable tip catheter in pulmonary vein ostium has deflectable tip located along distal end portion and ablation element disposed on distal end portion**

Abstract (Basic):

... An elongated catheter body has proximal and distal end portions. A guide - wire (922) lumen extends along at least a portion of a distal end portion (940) and terminates at a distal port. The guide - wire lumen is formed to slidably engage a guide - wire . A deflectable tip (916) is located along the distal end portion. An ablation element (918) is disposed on the distal end portion for ablating body tissue.

... diagnostic device within a body structure at location where a pulmonary vein extends from an atrium

...For positioning a therapeutic device such as a deflectable tip catheter in a body structures in combination with a guide - wire to facilitate the advancement of a circumferential ablation device into

a pulmonary vein ostium...

...a quick and easy manner. Capable of engaging the surrounding tissue to create a circumferential **lesion** for isolating a pulmonary vein from the posterior **atrial** wall of the heart thus providing a significant advancement in the treatment of **atrial fibrillation**.

...The drawing illustrates the movement of the deflectable tip portion of the deflectable tip **catheter** according to one embodiment of the present invention...

... **ablation** element (918...

... **guide - wire** (922

...Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-018/14** ...

International Patent Class (Additional): **A61B-018/00** ...

22/3,K/8 (Item 8 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014300799 \*\*Image available\*\*

WPI Acc No: 2002-121503/200216

Related WPI Acc No: 1995-215122; 1998-007592; 1998-216074; 1999-044350;  
1999-404363; 2001-145825; 2002-081841

XRPX Acc No: N02-091145

**Recording and ablation system for accessing cardiac chamber, prevents  
relative motion between guide wire and working catheter that has  
serially spaced electrodes**

Patent Assignee: AVITALL B (AVIT-I)

Inventor: AVITALL B

Number of Countries: 001 Number of Patents: 002

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020002329	A1	20020103	US 93161920	A	19931203	200216 B
			US 95487492	A	19950608	
			US 96593660	A	19960129	
			US 97968159	A	19971112	
			US 98154854	A	19980917	
			US 2000629208	A	20000731	
			US 2001939393	A	20010824	
US 6430426	B2	20020806	US 93161920	A	19931203	200259
			US 95487492	A	19950608	
			US 96593660	A	19960129	
			US 97968159	A	19971112	
			US 98154854	A	19980917	
			US 2000629208	A	20000731	
			US 2001939393	A	20010824	

Priority Applications (No Type Date): US 96593660 A 19960129; US 93161920 A  
19931203; US 95487492 A 19950608; US 97968159 A 19971112; US 98154854 A  
19980917; US 2000629208 A 20000731; US 2001939393 A 20010824

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020002329	A1		31	A61N-001/05	CIP of application US 93161920 CIP of application US 95487492 Div ex application US 96593660 Div ex application US 97968159 Div ex application US 98154854 Cont of application US 2000629208 CIP of patent US 5487385 CIP of patent US 5687723 Div ex patent US 5730127 Div ex patent US 5842984 Div ex patent US 6138043 Cont of patent US 6308091
US 6430426	B2			A61B-005/04	CIP of application US 93161920 CIP of application US 95487492 Div ex application US 96593660 Div ex application US 97968159 Div ex application US 98154854 Cont of application US 2000629208 CIP of patent US 5487385 CIP of patent US 5687723 Div ex patent US 5730127 Div ex patent US 5842984 Div ex patent US 6138043 Cont of patent US 6308091

Recording and ablation system for accessing cardiac chamber, prevents relative motion between guide wire and working catheter that has serially spaced electrodes

Abstract (Basic):

... A working catheter (32) which is extendable to protrude and be deployed from an opening in an outer catheter, is axially adjustable relative to a guide wire (36). A rider device slidably threads over the guide wire, such that working catheter portion near the rider, is adjustably flexed. The relative motion between the working catheter having serially spaced electrodes (34) and the guide wire, is prevented.

... For accessing cardiac chamber to create continuous linear lesions in chamber for performing treatment for cardiac arrhythmias such as atrial fibrillation and flutter.

...Disposition of working catheter within the chamber of heart is controlled easily, so that desired alignment at ablation site is achieved in shortest time...

...The figure shows a schematic view of atrial fibrillation mapping and ablation catheter.

...Working catheter (32...

... Guide wire (36

...Title Terms: ABLATE ;

International Patent Class (Main): A61B-005/04 ...



22/3,K/9 (Item 9 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014261143 \*\*Image available\*\*

WPI Acc No: 2002-081841/200211

Related WPI Acc No: 1995-215122; 1998-007592; 1998-216074; 1999-044350;  
1999-404363; 2001-145825; 2002-121503

XRPX Acc No: N02-060917

**Recording and ablation catheter system for treating patients with  
ventricular tachycardia , cardiac arrhythmia , has control system  
enabling signal reception from electrodes for mapping, for spot and  
linear ablation**

Patent Assignee: AVITALL B (AVIT-I)

Inventor: AVITALL B

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6308091	B1	20011023	US 93161920	A	19931203	200211 B
			US 95487492	A	19950619	
			US 96593660	A	19960129	
			US 97968159	A	19971112	
			US 98154854	A	19980917	
			US 2000629208	A	20000731	

Priority Applications (No Type Date): US 96593660 A 19960129; US 93161920 A  
19931203; US 95487492 A 19950619; US 97968159 A 19971112; US 98154854 A  
19980917; US 2000629208 A 20000731

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 6308091	B1	30	A61B-005/04	CIP of application US 93161920 CIP of application US 95487492 Div ex application US 96593660 Div ex application US 97968159 Cont of application US 98154854 CIP of patent US 5487385 CIP of patent US 5687723 Div ex patent US 5730127 Div ex patent US 5842984 Cont of patent US 6138043

**Recording and ablation catheter system for treating patients with  
ventricular tachycardia , cardiac arrhythmia , has control system  
enabling signal reception from electrodes for mapping, for spot and  
linear ablation**

Abstract (Basic):

... A control wire (299) is connected near a distal tip, of a  
working **catheter** (142), within a main **catheter** (147). The working  
**catheter** has flexible distal recording and **ablation** unit, with  
serially isolated electrodes (143). A **guide wire** (140) is  
associated with deployed working **catheter** . A control system enables  
signal reception from the electrodes for mapping and separate  
energization, to perform spot and **linear ablation** .

... For creating continuous **linear lesions** in **cardiac chamber**  
for treating patients with **ventricular tachycardia** and **cardiac**  
**arrhythmias** .

...The working **catheter** enables desired placement of electrodes...

...The figure shows the recording and **ablation catheter** system...

... Guide wire (140...

... Catheters (142,147

...Title Terms: **ABLATE** ;

International Patent Class (Main): **A61B-005/04**

22/3,K/10 (Item 10 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014189301 \*\*Image available\*\*  
WPI Acc No: 2002-009998/200201  
Related WPI Acc No: 2002-088738  
XRPX Acc No: N02-008349

Microwave ablation instrument e.g. catheter for cardiac  
arrhythmias , has horn antenna having inner and outer conductors which  
cooperatively emit electromagnetic field causing tissue ablation in  
predetermined direction

Patent Assignee: BERUBE D (BERU-I); AFX INC (AFXA-N)

Inventor: BERUBE D

Number of Countries: 001 Number of Patents: 002

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20010029368	A1	20011011	US 99333747	A	19990614	200201 B
			US 2001861027	A	20010518	
US 6527768	B2	20030304	US 99333747	A	19990614	200320
			US 2001861027	A	20010518	

Priority Applications (No Type Date): US 99333747 A 19990614; US 2001861027  
A 20010518

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20010029368	A1	12	A61B-018/18	Div ex application US 99333747
US 6527768	B2		A61B-018/18	Div ex application US 99333747 Div ex patent US 6287302

Microwave ablation instrument e.g. catheter for cardiac  
arrhythmias , has horn antenna having inner and outer conductors which  
cooperatively emit electromagnetic field causing tissue ablation in  
predetermined direction

Abstract (Basic):

... A transmission line (11) has two conductors (12,13) for  
transmitting microwave energy. An inner conductor (17) and an outer  
conductor (16) of a horn antenna (15) cooperate to emit  
electromagnetic field sufficiently strong to cause tissue ablation in  
direction away from flared interior wall of the outer conductor.

... An INDEPENDENT CLAIM is also included for horn antenna  
assembly...

...E.g. catheter , used as therapeutic ablation instrument for treatment  
of cardiac arrhythmias , cardiac disrhythmias and tachycardia ,  
especially for treatment of cancer...

...More concentrated electromagnetic field can be directed towards a region  
distal to the horn antenna thereby allowing for deeper penetration of  
biological tissues. Effective ablation area is increased while  
maintaining ablation accuracy of the targeted tissue...

...The figure shows the enlarged fragmental side elevation view of horn  
antenna cross-section...

...Transmission line (11...

...Horn antenna (15...

Title Terms: MICROWAVE ;

International Patent Class (Main): A61B-018/18

22/3,K/11 (Item 11 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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014052462 \*\*Image available\*\*  
WPI Acc No: 2001-536675/200159  
XRAM Acc No: C01-159838  
XRPX Acc No: N01-398578

**Balloon catheter device for treating arrhythmias , particularly aroxysmal atrial fibrillation , includes optical fiber for radial delivery of radiation, and extending through shaft and balloon**  
Patent Assignee: UNIV JOHNS HOPKINS (UYJO. ); BERGER R D (BERG-I); FRIED N M (FRIE-I); HALPERIN H R (HALP-I); LARDO A C (LARD-I); TSITLIK A (TSIT-I)  
Inventor: BERGER R D; FRIED N M; HALPERIN H R; LARDO A C; TSITLIK A; FRIED N

Number of Countries: 094 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200164123	A2	20010907	WO 2001US6526	A	20010228	200159 B
AU 200139964	A	20010912	AU 200139964	A	20010228	200204
US 20020052621	A1	20020502	US 2000185622	P	20000229	200234
			US 2001796571	A	20010228	

Priority Applications (No Type Date): US 2000185622 P 20000229; US 2001796571 A 20010228

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200164123	A2	E	23	A61B-018/24	
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Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

AU 200139964	A			A61B-018/24	Based on patent WO 200164123
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US 20020052621	A1			A61M-029/00	Provisional application US 2000185622
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**Balloon catheter device for treating arrhythmias , particularly aroxysmal atrial fibrillation , includes optical fiber for radial delivery of radiation, and extending through shaft and balloon**

Abstract (Basic):

... A balloon **catheter** device comprises a shaft having a proximal end (4) and a distal end (6); a...

... INDEPENDENT CLAIMS are also included for (A) a medical device kit comprising the inventive **catheter** devices; and (B) a method for treating a patient suffering from **arrhythmias** , particularly **atrial fibrillation** , comprising treating the pulmonary vein of the patient with radially emitted visible or near-infrared...

...For treating **arrhythmias** , particularly aroxysmal **atrial fibrillation** .

...

....radial delivery matches the cylindrical anatomy of the PV. The device may be used to **electrically isolate** the PV from the left **atrium** of the heart by creating transmural, continuous, and circumferential **lesions** at the PV ostia in a single application. The use of near-infrared laser radiation enables deeper penetration into **cardiac** tissue as compared to **radio frequency** , provides more uniform tissue heating and less probability of complications such as tissue

vaporization, endothelial

Technology Focus:

... Preferred Component: The balloon **catheter** device includes a sheath (2). A valve (12) is on the proximal end of the...  
...to a balloon inflation source. A syringe is insertable in the second valve. An inflation **lumen** is provided through which the balloon inflation material travels to the balloon. A **guidewire** is provided for steerable guidance of the device. The device has a laser that provides approximately 10-100 W for producing thermal **lesions** in the pulmonary veins (PV) of a patient. The laser is high-power diode laser  
...

...4 mm or less than 10 Fr, inner diameter of 3-6 Fr. The inflation **lumen** has a diameter of 100-500  $\mu\text{m}$ . The balloon is inflated to 5 cc, 2...

...Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-018/24** ...

22/3,K/12 (Item 12 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

013923146 \*\*Image available\*\*  
WPI Acc No: 2001-407359/200143  
XRAM Acc No: C01-123362  
XRPX Acc No: N01-301334

Catheter for ablation procedure includes flexible distal member  
inserted into first vessel of patient

Patent Assignee: FIDUS MEDICAL TECHNOLOGY CORP (FIDU-N)  
Inventor: DOWNAR E; KNOPP P G; LARKIN K T; NGUYEN H P H; WOODARD R E  
Number of Countries: 001 Number of Patents: 001  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6251128	B1	20010626	US 98144962	A	19980901	200143 B

Priority Applications (No Type Date): US 98144962 A 19980901

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 6251128	B1	25	A61F-002/00	

Catheter for ablation procedure includes flexible distal member  
inserted into first vessel of patient

Abstract (Basic):

... A **catheter** which may be configured as a **loop** in the **cardiac** chamber during an **ablation** procedure, and a method of use for such a **catheter** , is new.

... According to one aspect of the present invention, an **ablation catheter** includes a flexible distal member inserted into a first vessel in the body of a...

...that is greater than or equal to the flexibility of the flexible distal member. The **catheter** also includes a transmission **line** which is at least partially disposed within the elongated flexible tubular member. A proximal end of the transmission **line** is suitable for connection to an electromagnetic energy source. The **catheter** further includes a transducer that is coupled to the transmission **line** , and is arranged to generate an electric field sufficiently strong to cause tissue **ablation** . The distal portion of the flexible distal member is arranged to protrude from a second...

...patient while at least part of the elongated flexible tubular member is located in a **cardiac** chamber of the heart of the patient...

...Used for the treatment of medical problems such as **cardiac arrhythmias** , **cardiac** disrhythmias, and **tachycardia** .

...The **ablation catheter** systems uses electromagnetic energy inn the **microwave** frequency range to **ablate** internal bodily tissues. The **catheter** may be manipulated to form a **loop** within a **cardiac** chamber to facilitate the **ablation** of **cardiac** tissue...

...Fig .1 is a diagrammatic representation of a **loop catheter** in accordance with the invention...

...overall **loop catheter** (150...

... **antenna** section (162

*See  
Fig.  
5,  
US  
version*

Technology Focus:

... material selected from the group consisting of stainless steel, polypropylene, polycarbonate, and polyethylene. The flexible **catheter** member is made from at least one of the following materials: PEBAX resin, polyolefins, fluoropolymers...

Title Terms: **CATHETER** ;

22/3,K/13 (Item 13 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

11 good

013523110 \*\*Image available\*\*  
WPI Acc No: 2001-007316/200101  
XRPX Acc No: N01-005240

Positioning system to guide catheter to location where pulmonary vein extends from left atrium of patient, has deflection device joined with sheath to direct guide wire to pulmonary vein on left atrium

Patent Assignee: ATRIONIX INC (ATRI-N); SCHAER A K (SCHA-I)

Inventor: LESH M D; SCHAER A K

Number of Countries: 093 Number of Patents: 006

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200067830	A1	20001116	WO 2000US13191	A	20000511	200101 B
AU 200051331	A	20001121	AU 200051331	A	20000511	200112
EP 1177008	A1	20020206	EP 2000935946	A	20000511	200218
			WO 2000US13191	A	20000511	
US 20030083613	A1	20030501	US 99133807	P	19990511	200331
			US 2000569734	A	20000511	
			US 2002313736	A	20021206	
US 6758830	B1	20040706	US 99133807	P	19990511	200444
			US 2000569734	A	20000511	
AU 770121	B2	20040212	AU 200051331	A	20000511	200453

see claims

Priority Applications (No Type Date): US 99133807 P 19990511; US 2000569734 A 20000511; US 2002313736 A 20021206

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200067830 A1 E 34 A61M-025/06

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW

AU 200051331 A Based on patent WO 200067830

EP 1177008 A1 E A61M-025/06 Based on patent WO 200067830

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI

US 20030083613 A1 A61M-037/00 Provisional application US 99133807

Cont of application US 2000569734

US 6758830 B1 A61M-035/00 Provisional application US 99133807

AU 770121 B2 A61M-025/06 Previous Publ. patent AU 200051331

Based on patent WO 200067830

Positioning system to guide catheter to location where pulmonary vein extends from left atrium of patient, has deflection device joined with sheath to direct guide wire to pulmonary vein on left atrium

Abstract (Basic):

... g. a guiding introducer (10), is removably engaged with a trans septal sheath. A deflectable guide wire or e.g. a balloon anchor wire, is introduced into the sheath and is led to the pulmonary vein on the left atrium by the deflection device. The guide wire facilitates positioning of an ablation catheter at the pulmonary vein.

... For guiding ablation catheter or other medical device to a location where pulmonary veins extend from left atrium of patient.



Also used in treatment of **atrial fibrillation** or in other condition e.g. heart **flutter** . Also used in **ablation** of e.g. fallopian **tube** cysts...

...Ensures positioning of both ends of **ablation** element e.g. **ablation catheter** , at ostiums of adjoining pulmonary veins of left **atrium** . Enables securing of **ablation** element between anchors; enabling element to form **linear ablation** track along length of tissue between anchors while maintaining contact with **atrial** wall...

...isometric view, partly in cross=section, of one example of a guiding introducer of an **ablation catheter** positioning system...

...Title Terms: **CATHETER** ;

International Patent Class (Additional): **A61B-018/14** ...

22/3,K/14 (Item 14 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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*Some of the inventors*

013360613 \*\*Image available\*\*  
WPI Acc No: 2000-532552/200048  
Related WPI Acc No: 2004-118192; 2004-497634  
XRPX Acc No: N00-393932

Electrical hollow coaxial cable for use in medical field, has outer conductor made of electrically conductive braided material or thin film material, over inner conductor provided with axial lumen

Patent Assignee: LAW M (LAWM-I); LEUNG G L (LEUN-I); ORMSBY T C (ORMS-I); MEDWAVES INC (MEDW-N)

Inventor: LAW M; LEUNG G L; ORMSBY T C

Number of Countries: 085 Number of Patents: 008

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200035363	A1	20000622	WO 99US29148	A	19991208	200048 B
AU 200031152	A	20000703	AU 200031152	A	19991208	200051
EP 1054639	A1	20001129	EP 99965180	A	19991208	200063
			WO 99US29148	A	19991208	
US 6190382	B1	20010220	US 98211188	A	19981214	200112
CN 1290148	A	20010404	CN 99802890	A	19991208	200140
KR 2001040944	A	20010515	KR 2000708865	A	20000812	200167
JP 2002532132	W	20021002	WO 99US29148	A	19991208	200279
			JP 2000587685	A	19991208	
TW 495354	A	20020721	TW 2000109908	A	20000523	200332 N

Priority Applications (No Type Date): US 98211188 A 19981214; TW 2000109908 A 20000523

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200035363 A1 E 37 A61B-018/04

Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

AU 200031152 A Based on patent WO 200035363

EP 1054639 A1 E Based on patent WO 200035363

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

JP 2002532132 W 37 A61B-018/14 Based on patent WO 200035363

TW 495354 A A61B-017/36

Electrical hollow coaxial cable for use in medical field, has outer conductor made of electrically conductive braided material or thin film material, over inner conductor provided with axial lumen

Abstract (Basic):

... An electrical hollow cable for conducting radio frequency energy has an inner conductor with an axial lumen, made of electrically conductive wire mesh. An outer conductor made of electrically conductive braided material...

... For radio frequency catheter systems used for ablating biological tissues in body vessels e.g. arteries or veins of patients, for the treatment of cardiac arrhythmias.

...

...Eliminates the need for repetitive pin-point precision placement of

ablation catheter electrodes and places a radio frequency antenna conveniently along the locus of an antenna guide which defines the tissue ablation pathway. Ensures a continuous ablation pathway and reduces the risk of electrical impulse leakage between ablated spots. Achieves linear lesions without the need for open heart surgery. Obtains a desirable level of stiffness and torsional strength for the catheter, by adding braiding reinforcement to the tubular body. Allows the catheter to advance and negotiate through a body vessel, and enables torque transfer along the length of the catheter.

...

...The figure shows the conceptual diagram of RF based catheter ablation system

...Title Terms: LUMEN

International Patent Class (Main): A61B-017/36 ...

... A61B-018/04 ...

... A61B-018/14

International Patent Class (Additional): A61B-017/00 ...

... A61B-018/18

22/3,K/15 (Item 15 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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*good!!*

013240238 \*\*Image available\*\*  
WPI Acc No: 2000-412112/200035  
Related WPI Acc No: 2000-422844; 2002-507736  
XRPX Acc No: N00-308074

Intracardiac grasp catheter for intracardiac mapping and tissue  
ablation has distal end preformed to small curve that can be deflected  
to a hook shape to lock onto edge of heart chamber, ring electrodes  
ablate and map heart wall

Patent Assignee: BARD INC C R (BRDC )  
Inventor: FALWELL G S; GIBSON C A; MCRURY I D; PETERSON M C; WANG P J  
Number of Countries: 023 Number of Patents: 008  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200032129	A1	20000608	WO 99US28233	A	19991123	200035 B
US 6178354	B1	20010123	US 98203922	A	19981202	200107
EP 1133264	A1	20010919	EP 99961858	A	19991123	200155
			WO 99US28233	A	19991123	
US 6319250	B1	20011120	US 98197812	A	19981123	200174
US 20020019630	A1	20020214	US 98197812	A	19981123	200214
			US 2001981543	A	20011017	
JP 2002531164	W	20020924	WO 99US28233	A	19991123	200278
			JP 2000584829	A	19991123	
US 20030004509	A1	20030102	US 98197812	A	19981123	200305
			US 2001981543	A	20011017	
			US 2002234675	A	20020903	
US 6572611	B1	20030603	US 98197812	A	19981123	200339
			US 99434599	A	19991105	

Priority Applications (No Type Date): US 99434599 A 19991105; US 98197812 A  
19981123; US 98203922 A 19981202; US 2001981543 A 20011017; US 2002234675  
A 20020903

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200032129	A1	E	47	A61B-018/14	
				Designated States (National): CA JP MX US	
				Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE	
US 6178354	B1			A61N-001/05	
EP 1133264	A1	E		A61B-018/14	Based on patent WO 200032129
				Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE	
US 6319250	B1			A61B-018/18	
US 20020019630	A1			A61B-018/14	Cont of application US 98197812 Cont of patent US 6319250
JP 2002531164	W		57	A61B-005/0408	Based on patent WO 200032129
US 20030004509	A1			A61B-018/14	Cont of application US 98197812 Cont of application US 2001981543 Cont of patent US 6319250
US 6572611	B1			A61B-018/14	CIP of application US 98197812 CIP of patent US 6319250

Intracardiac grasp catheter for intracardiac mapping and tissue  
ablation has distal end preformed to small curve that can be deflected  
to a hook shape to lock onto edge of heart chamber, ring electrodes  
ablate and map heart wall

Abstract (Basic):

*See  
figures  
in these  
two  
"US"  
versions*

... The **catheter** (300) has a proximal shaft (311) that is more rigid than the distal shaft (313). The distal tip (316) of the **catheter** has a preformed **curve** (360) with an inner angle (alpha) of 20-100degrees. **Guidewires** can convert the tip to a hook shape that can lock onto an edge of the heart chamber. Ring electrodes (314) map or **ablate** tissue from the heart chamber.

... An INDEPENDENT CLAIM is also included for the method of treating **cardiac arrhythmia** or mapping intracardiac tissue using a **catheter** of the invention...

...Treating **cardiac arrhythmia** by mapping and tissue **ablation** .

...

...The end of the **catheter** can be converted to a hook that makes a secure contact to the **isthmus** of tissue between the interior vena cava and the tricuspid annulus...

...The drawing is a schematic illustration of part of the **catheter** in a non-deflected and a deflected condition...

... **Catheter** (300)...

...Tip of **catheter** (316)...

...Curved section of **catheter** (360)

...Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-005/0408** ...

... **A61B-018/14** ...

... **A61B-018/18**

International Patent Class (Additional): **A61B-005/0478** ...

... **A61B-005/0492** ...

... **A61B-018/12**

22/3,K/16 (Item 16 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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*Good!*

013204175 \*\*Image available\*\*  
WPI Acc No: 2000-376048/200032  
Related WPI Acc No: 2003-046879  
XRPX Acc No: N00-282454

Electro-physiological diagnosis and therapy for atrial fibrillation ,  
using magnetic resonance-guided imaging for accurately locating ablation  
catheter to perform cardiac linear lesions  
Patent Assignee: UNIV JOHNS HOPKINS (UYJO ); ATALAR E (ATAL-I); BERGER R D  
(BERG-I); BOTTMLEY P (BOTT-I); CALKINS H (CALK-I); HALPERIN H R (HALP-I);  
LARDO A C (LARD-I); SUSIL R C (SUSI-I); UNIV JOHNS HOPKINS SCHOOL  
MEDICINE (UYJO ); LARDO A (LARD-I); LIMA J (LIMA-I); MCVEIGH E R  
(MCVE-I)

Inventor: ATALAR E; BERGER R D; CALKINS H; HALPERIN H R; LARDO A; LIMA J;  
MCVEIGH E R; BOTTMLEY P; LARDO A C; SUSIL R C

Number of Countries: 086 Number of Patents: 007

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200025672	A1	20000511	WO 99US25858	A	19991104	200032 B
AU 200016051	A	20000522	AU 200016051	A	19991104	200040
EP 1126784	A1	20010829	EP 99958755	A	19991104	200150
			WO 99US25858	A	19991104	
US 20030050557	A1	20030313	US 98106965	P	19981104	200321
			US 99428990	A	19991029	
			US 2001283725	P	20010413	
			US 2002123534	A	20020415	
US 20030199755	A1	20031023	US 99428990	A	19991029	200370
			US 2003424093	A	20030428	
US 6701176	B1	20040302	US 98106965	P	19981104	200417
			US 99428990	A	19991029	
US 20040167392	A1	20040826	US 98106965	P	19981104	200457
			US 99428990	A	19991029	
			US 2004791622	A	20040302	

*see col. 7, 10+  
in "US"  
version*

Priority Applications (No Type Date): US 99428990 A 19991029; US 98106965 P  
19981104; US 2001283725 P 20010413; US 2002123534 A 20020415; US  
2003424093 A 20030428; US 2004791622 A 20040302

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200025672	A1	E	37	A61B-005/055	
Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW					
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW					
AU 200016051	A				Based on patent WO 200025672
EP 1126784	A1	E		A61B-005/055	Based on patent WO 200025672
Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI					
US 20030050557	A1			A61B-005/05	Provisional application US 98106965
CIP of application US 99428990					
Provisional application US 2001283725					
US 20030199755	A1			A61B-005/05	Div ex application US 99428990
US 6701176	B1			A61B-005/055	Provisional application US 98106965
US 20040167392	A1			A61B-005/55	Provisional application US 98106965

Cont of application US 99428990

Cont of patent US 6701176

**Electro-physiological diagnosis and therapy for atrial fibrillation ,  
using magnetic resonance-guided imaging for accurately locating ablation  
catheter to perform cardiac linear lesions**

Abstract (Basic):

- ... The system uses magnetic resonance imaging for improving accuracy obtainable in **electro**-physiological **surgical** procedures, in particular for **atrial fibrillation** within a patient's heart. An imaging **catheter** is invasively introduced, which includes a **radiofrequency ( RF ) antenna** section (19) for receiving magnetic resonance signals, and diagnostic electrodes (11) for receiving electrical potentials.
- ... The **catheter** is used with an imaging scanner for guidance and to enable location images, which may be 3-dimensional, to be produced during diagnostic/therapeutic procedures. For **cardiac ablation** application, the length of the invasive part of the **catheter** is at least 1200 mm, so that the tip may be placed within the heart...
- ...For applying magnetic resonance imaging techniques for positioning a diagnostic/therapeutic **catheter** very accurately in 3-dimensional space in a **cardiac** environment, without using radiation such as X-ray fluoroscopy...
- ...The system offers particular advantage in procedures for **ablating** ischemic, idiopathic **ventricular** and ectopic **atrial tachycardias** , and for **atrial flutter / fibrillation** , reducing duration of required surgical procedure, and the risk of possible complications...
- ...drawing shows a cross-sectional view of the tip of a combined electro-physiological/imaging **antenna catheter** , in accordance with a preferred embodiment of the inventive system...
- ... **RF antenna** (3...
- ... **Antenna body** (19...
- ... **Catheter steering wire** (5...
- ... **Ablating tip** (13...
- ...Flexible dipole **antenna** helical whip section (21
- ...Title Terms: **ATRIUM** ;
- International Patent Class (Main): **A61B-005/05** ...
- ... **A61B-005/055** ...
- ... **A61B-005/55**

22/3,K/17 (Item 17 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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012113819 \*\*Image available\*\*  
WPI Acc No: 1998-530731/199845  
XRPX Acc No: N98-414135

Conformal positioning assembly for microwave ablation catheter -  
has shape memory wire positioned at distal portion of catheter adjacent  
to transducer so that it deforms when distal portion of catheter  
deforms

Patent Assignee: FIDUS MEDICAL TECHNOLOGY CORP (FIDU-N)

Inventor: MOSS J F; NGUYEN H P H; STURZU P

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 5810803	A	19980922	US 96732045	A	19961016	199845 B

Priority Applications (No Type Date): US 96732045 A 19961016

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 5810803	A	16	A61B-017/39	

Conformal positioning assembly for microwave ablation catheter -

...

...has shape memory wire positioned at distal portion of catheter  
adjacent to transducer so that it deforms when distal portion of  
catheter deforms

...Abstract (Basic): The assembly (200) includes an antenna (206) with a  
proximal end (208) and a distal end (210). The proximal end is grounded  
to a shield of transmission line. The transmission line which is  
supported within a distal shaft (222) is coaxial and coupled to an  
external electromagnetic energy source. The distal end of the antenna  
is attached to center conductor (224) of the transmission line. A  
transducer is coupled to the transmission line for generating a  
strong electric field to cause tissue ablation.

...

...A shape memory metal wire (228) is positioned at the distal portion  
of the catheter adjacent to the transducer. The shape memory wire  
which is made of a material containing chromium, molybdenum, copper,  
beryllium, steel and nickel-titanium, deforms when the distal portion  
of the catheter deforms...

...USE - For treatment of cardiac arrhythmias, cardiac disrhythmias,  
tachycardia.

...

...ADVANTAGE - Is suited for non-cardiac ablation applications as well

...Title Terms: MICROWAVE ;

International Patent Class (Main): A61B-017/39



22/3,K/18 (Item 18 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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012029006 \*\*Image available\*\*  
WPI Acc No: 1998-445916/199838  
XRPX Acc No: N98-347610

Microwave mapping ablation catheter for therapy of cardiac arrhythmias, cardiac dysrhythmias and tachycardia - has set of mapping electrode bands longitudinally arranged on surface of flexible tube, which are implanted with ions and each of which has electrodes for mapping of tissues and locating tissue to be ablated

Patent Assignee: FIDUS MEDICAL TECHNOLOGY CORP (FIDU-N)  
Inventor: CAMPBELL T H; MEAD R H; SEDDIQUI F R; STURZU P  
Number of Countries: 001 Number of Patents: 001  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 5788692	A	19980804	US 95497941	A	19950630	199838 B

Priority Applications (No Type Date): US 95497941 A 19950630

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 5788692	A	12	A61B-017/39	

Microwave mapping ablation catheter for therapy of cardiac arrhythmias, cardiac dysrhythmias and tachycardia - ...  
...has set of mapping electrode bands longitudinally arranged on surface of flexible tube, which are implanted with ions and each of which has electrodes for mapping of tissues and locating tissue to be ablated

...Abstract (Basic): The catheter (50) comprises a flexible tube (51) insertable into the patient's body, provided with distal and proximal portions. A coaxial transmission line (53) with proximal and distal ends, is slidably received inside the tube, where its proximal end is connected to a microwave energy source. A set of mapping electrode bands (67) are longitudinally arranged along surface of the tube. The electrode bands are ion implanted, on the tube such that they are flexible. Multiple electrically isolated electrodes are included in the electrode bands configured to enable mapping of tissues for identifying a location of tissue to be ablated.

...A microwave antenna is received inside the tube and is slid together with the transmission line, longitudinally. Owing to its movement, the antenna is positioned relative to the mapping electrode bands. After locating the tissue to be ablated by the mapping of vessel by electrodes, the antenna and transmission line are slid relative to the electrodes, within the tube. Then, the antenna is appropriately positioned for ablation of the identified tissue...

...USE - For locating portion of cardiac tissue to be ablated, prior to ablation operation. For use in non-cardiac ablation application, as well...

...ADVANTAGE - Monitors electrophysiological signals using electrodes for identifying appropriate ablation position. Shortens ablation operation time as both mapping and ablation are performed, simultaneously. Uses transducer coupled to transmission line for generating sufficient electric field to cause ablation of tissue

Title Terms: MICROWAVE ;

International Patent Class (Main): A61B-017/39

International Patent Class (Additional): A61B-005/042 ...

22/3,K/19 (Item 19 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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011843462 \*\*Image available\*\*  
WPI Acc No: 1998-260372/199823  
XRPX Acc No: N98-205309

**Anchoring tip assembly for microwave ablation catheter for treatment of cardiac arrhythmias , e.t.c. - has flexible anchoring tip extension attached immovably to distal portion of flexible tubular member, and helical antenna coil radiating electromagnetic energy in microwave frequency range**

Patent Assignee: FIDUS MEDICAL TECHNOLOGY CORP (FIDU-N)

Inventor: MOSS J F; NGUYEN H P; STURZU P

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 5741249	A	19980421	US 96755998	A	19961125	199823 B

Priority Applications (No Type Date): US 96755998 A 19961125

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
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US 5741249	A	18	A61B-017/39	
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**Anchoring tip assembly for microwave ablation catheter for treatment of cardiac arrhythmias , e.t.c...**

**...flexible anchoring tip extension attached immovably to distal portion of flexible tubular member, and helical antenna coil radiating electromagnetic energy in microwave frequency range**

...Abstract (Basic): which is inserted into a vessel in the body of a patient. A coil-shaped **antenna** (206) made of either spring steel, beryllium copper or silver-plated copper is wound around...

...centre conductor (224) and a shape memory alloy wire (228). The outer diameter of the **antenna** coil is within 0.08-0.09 inches. The **antenna** has a proximal end (208) which is connected to a shield of a **transmission line** (220). A transducer coupled to the **transmission line** generates an electric field sufficiently strong to cause tissue **ablation**. A distal end (210) of the **antenna** is attached to the centre conductor. The **transmission line** supported within a distal shaft (222) is coupled to an electromagnetic energy source...

...and a pair of proximal electrodes (234) made of same material and which assist in **catheter** positioning during **ablation**, are arranged within the tubular member. An anchoring tip extension (240) made of flexible dielectric...

...USE - For treatment of **cardiac arrhythmias**, **cardiac dysrhythmias**, and **tachycardia**.

...ADVANTAGE - Enables **ablation** of internal body tissues using electromagnetic energy of **microwave** frequency. Avoids slippage of **catheter** during **ablation** by fixing anchoring tip extension in crevices. Enables proper orientation of **catheter** tip to heart wall. Eases repositioning of **catheter** tip by dislodging anchoring tip extension from heart wall

...Title Terms: **MICROWAVE** ;

International Patent Class (Main): **A61B-017/39**

22/3,K/20 (Item 20 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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Good!!

011247212 \*\*Image available\*\*  
WPI Acc No: 1997-225115/199720  
XRPX Acc No: N97-186298

Pre-shaped cardiac catheter for treating atrial fibrillation -  
has array of spaced apart electrodes which may be activated remotely to  
preselected current level for set time interval to ablate target of  
cardiac circuitry adjacent electrodes

Patent Assignee: MUNSIF A (MUNS-I)

Inventor: MUNSIF A

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No.	Kind	Date	Applicat No	Kind	Date	Week
US 5617854	A	19970408	US 94264069	A	19940622	199720 B

Priority Applications (No Type Date): US 94264069 A 19940622

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 5617854	A	46	A61B-017/36	

Pre-shaped cardiac catheter for treating atrial fibrillation -

...  
...electrodes which may be activated remotely to preselected current level  
for set time interval to ablate target of cardiac circuitry adjacent  
electrodes

...Abstract (Basic): The catheter includes a pre-shaped first curved  
portion for positioning around the ostium of coronary sinus and a  
second curved portion for maintaining the first curved portion in its  
desired position. A catheter assembly, including a guide - wire and  
a preshaped catheter are introduced to a location proximal the  
atrium . As the guide - wire is withdrawn from within the catheter ,  
the catheter assumes its preshaped form at the target location.  
Alternatively, a catheter assembly, with or without a guide-wire, may  
be introduced to the target ablation site via a catheter sheath.  
The catheter includes an array of spaced apart electrodes on at least  
a portion of the catheter . Each electrode may be activated remotely  
to a preselected current level for a preselected time interval to  
ablate a target portion of cardiac circuitry adjacent the electrodes

...Title Terms: CARDIAC ;

International Patent Class (Main): A61B-017/36

International Patent Class (Additional): A61B-005/042

22/3,K/21 (Item 21 from file: 350)  
DIALOG(R) File 350:Derwent WPIX  
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010313864 \*\*Image available\*\*

WPI Acc No: 1995-215122/199528

Related WPI Acc No: 1998-007592; 1998-216074; 1999-044350; 1999-404363;  
2001-145825; 2002-081841; 2002-121503

XRPX Acc No: N95-168688

Atrial mapping and ablation catheter - has multi-electrode working  
catheter shapes which are deployed from main catheter to contact  
desired inner wall surface of atrial cardiac chamber to produce  
linear lesions

Patent Assignee: AVITALL B (AVIT-I)

Inventor: AVITALL B

Number of Countries: 020 Number of Patents: 008

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9515115	A1	19950608	WO 94US13932	A	19941201	199528 B
AU 9512654	A	19950619	AU 9512654	A	19941201	199540
US 5487385	A	19960130	US 93161920	A	19931203	199611
EP 731665	A1	19960918	WO 94US13932	A	19941201	199642
			EP 95903675	A	19941201	
JP 9506017	W	19970617	WO 94US13932	A	19941201	199734
			JP 95515799	A	19941201	
AU 685559	B	19980122	AU 9512654	A	19941201	199811
JP 3237849	B2	20011210	WO 94US13932	A	19941201	200203
			JP 95515799	A	19941201	
CA 2177982	C	20020910	CA 2177982	A	19941201	200264
			WO 94US13932	A	19941201	

Priority Applications (No Type Date): US 93161920 A 19931203

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9515115	A1	E	20	A61B-005/04	
				Designated States (National): AU CA JP	
				Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LU MC NL PT SE	
AU 9512654	A			A61B-005/04	Based on patent WO 9515115
US 5487385	A		9	A61B-005/04	
EP 731665	A1	E	20	A61B-005/04	Based on patent WO 9515115
				Designated States (Regional): DE ES FR GB IT NL	
JP 9506017	W		31	A61B-005/0408	Based on patent WO 9515115
AU 685559	B			A61B-005/04	Previous Publ. patent AU 9512654
					Based on patent WO 9515115
JP 3237849	B2		8	A61B-005/0408	Previous Publ. patent JP 9506017
					Based on patent WO 9515115
CA 2177982	C	E		A61B-017/36	Based on patent WO 9515115
				Atrial mapping and ablation catheter - ...	

...has multi-electrode working catheter shapes which are deployed from  
main catheter to contact desired inner wall surface of atrial  
cardiac chamber to produce linear lesions

...Abstract (Basic): The catheter system includes an array of readily  
controlled electrodes (143) which are deployed to contact the inner  
wall surface of the right atrial chamber in a manner that allows them  
to adapt to the endocardial surface of the atrium and enables  
recording or mapping of electrical impulses. The catheter provides  
sustained contact such that linear lesions can be produced from the

array of mapping and **ablation** electrodes serially spaced along the working **catheter** shape, using electrical heating or **RF ablation** energy...

- ...The working **catheter** section is deployed from a main **catheter** or sheath and assumes several shapes, the control of which may be independent of or with reference to the slidable attachment of one or both ends of the working **catheter** section to a **guidewire** of other **catheter** mounted element...
- ...USE/ADVANTAGE - **Atrial fibrillation** electrical mapping and **ablation** system for creating **linear lesions** in right **atrial** chamber of heart. Provides **catheter** shapes capable of being modified to address internal surfaces of varying contours...
- ...Abstract (Equivalent): A method of mapping and **ablating** surface tissue in the right **atrial cardiac** chamber comprising the steps of...
- ...a) navigating a main **catheter** or sheath carrying a deployable flexible distal working **catheter** section through the vascular system of a patient of interest...
- ...b) causing the distal end of the **catheter** to enter the right **atrial** chamber optionally through a vessel selected from the group consisting of the superior vena cava...
- ...c) wherein said main **catheter** or sheath comprises...
- ...1) a vascular navigating **guidewire** disposed to protrude from a distal end of said main **catheter** or sheath...
- ...2) a single member flexible working **catheter** section having a proximal and a distal end and adapted to be deployed from said main **catheter** or sheath via a **lumen** therein for containing said working **catheter** section and a plurality of spaced separately connected serially situated electrodes on said single member working **catheter** section...
- ...3) means for causing said working **catheter** section to assume an arcuate shape of controlled **curvature** for contacting an internal surface of said chamber and assuming an adjustable posture enabling positioning for the production of substantially **linear ablation lesions** along a predetermined **line** of the chamber surface using said plurality of spaced electrodes...
- ...d) causing the distal area of the working **catheter** section to assume a controlled **curvature** in contact with a desired inner **atrial** surface such that a relatively **linear ablation lesion** can be formed by energizing a plurality of said spaced serial electrodes...
- ...e) adjusting and positioning said single member working **catheter** section to **ablate** desired areas of said inner **atrial** surface...
- ...f) **ablating** tissue to form **linear lesions** where indicated; and...

Title Terms: **ATRIUM** ;

International Patent Class (Main): **A61B-005/04** ...

... **A61B-005/0408** ...

... **A61B-017/36**

International Patent Class (Additional): **A61B-005/0402** ...

... **A61B-005/0478** ...

... A61B-005/0492 ...

... A61B-017/39 ...

... A61B-018/12

22/3,K/24 (Item 24 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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007056051

WPI Acc No: 1987-056048/198708

XRPX Acc No: N87-042522

Tachycardia or cardiac disrhythmia treatment using catheter -  
performing selective ablation of cardiac tissue by means of HF  
electromagnetic energy

Patent Assignee: RCA CORP (RADC )

Inventor: GREENSPON A J; ROSEN A; WALINSKY P

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 4641649	A	19870210	US 85792895	A	19851030	198708 B

Priority Applications (No Type Date): US 85792895 A 19851030

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 4641649	A	10		

Tachycardia or cardiac disrhythmia treatment using catheter - ...

...performing selective ablation of cardiac tissue by means of HF  
electromagnetic energy

...Abstract (Basic): The catheter includes a flexible coaxial  
transmission line (coax) terminated by an antenna . The antenna  
and coax are introduced into a chamber of the heart. The antenna is  
brought into contact with a wall of the heart. Action potentials  
generated by the heart are coupled through the antenna and the cable  
to a standard electrocardiograph appts. for display. Other electrodes  
placed about the body also produce action potentials which are  
displayed by the electrocardiograph. The position of the antenna in  
the chamber of the heart is adjusted with the aid of the displayed  
action potentials until the antenna is in contact with the region to  
be ablated or injured as indicated by its characteristic electrical  
signature...

...When the antenna is adjacent to or in contact with the desired  
location, radio frequency or microwave frequency electrical  
energy is applied to the proximal end of and through the coax to the  
antenna . The action potentials may be viewed while the electrical  
energy is applied. The power of...

Title Terms: TACHYCARDIA ;



Set	Items	Description
S1	166429	ABLAT? OR CRYOABLAT? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR MICROWAV? OR MICRO() (WAVE? OR WAVING) OR ELECTROSURG? - OR ELECTRO?(2N)SURG? OR ELECTRICAL?()ISOLAT?
S2	86205	ATRIA? OR ATRIU? OR VENTRI? OR CARDI? OR ISTHMUS? OR INTRA-ATRI? OR INTRAVENTR? OR TRANSATRI? OR TRANSVENTR? OR MITRA?(3-N)VALV? OR EPICARD? OR MYOCARD?
S3	17832	FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUTTER? OR (IRREGULAR? OR RAPID?) () (HEARTBEAT? OR HEART()BEAT?) - OR DISRHYTHM?
S4	393453	CATHETER? OR CANULA? OR CANNULA? OR CANNULLA? OR CANULLA? - OR LUMEN? OR TUBE? OR TUBING?
S5	80367	ANTENNA? OR (COAXIAL? OR CO()AXIAL?) ()CABL? OR GUIDEWIR? OR GUIDE() (WIRE? OR WIRING)
S6	521203	USHAP? OR U()SHAP? OR CURV? OR LOOP? OR (180 OR ONE()HUNDRED(2N)EIGHTY) ()DEGREE? OR UTURN? OR U()TURN? OR (HAIRPIN? OR -HAIR()PIN) ()TURN?
S7	65970	PRESHAP? OR PRE()SHAP? OR PREFORM? OR PRE()FORM? OR MEMORY-()METAL? OR NITINOL? OR MARTEN? OR AUSTEN?
S8	1011524	LINE OR LINES OR LINED OR LINEAR? OR LESION? OR CURVILINE? OR SCORE? OR SCORING? OR SCAR? OR ULCER? OR SCORIF?
S9	1365417	METHOD? ?
S10	1139951	SYSTEM?
S11	1055979	PROCESS??
S12	466623	PROCEDUR?
S13	600348	TECHNIQUE?
S14	55431	IC=A61B?
S15	373	S1(20N)S2 AND S3 AND S4 AND S5
S16	235	S15 AND S14
S17	372	S15 AND S9:S13
S18	373	S15:S17
S19	61	S18 AND S6:S7(10N)S5
S20	56	S19 AND S8
S21	61	S19:S20
S22	61	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 348:EUROPEAN PATENTS 1978-2004/Sep W01

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File 349:PCT FULLTEXT 1979-2002/UB=20040916,UT=20040909

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22/3,K/7 (Item 7 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
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01616196

**Radio frequency pulmonary vein isolation**

**Isolierung der pulmonalen Vene durch Radiofrequenz**

**Isolation de la veine pulmonaire a l'aide d'une radiofrequence**

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PRIORITY (CC, No, Date): US 62698 020131

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EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO

INTERNATIONAL PATENT CLASS: A61B-018/14

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Figure number on first page: 6

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SPEC A	(English)	200332	6192
Total word count - document A			6914
Total word count - document B			0
Total word count - documents A + B			6914

INTERNATIONAL PATENT CLASS: A61B-018/14

...ABSTRACT A1

A **catheter** introduction apparatus provides a radially expandable helical coil as a radiofrequency emitter. In one application...

...contact with the inner wall of the pulmonary vein. The coil is energized by a **radiofrequency** generator, and a circumferential **ablation** lesion is produced in the **myocardial** sleeve of the pulmonary vein, which effectively blocks electrical propagation between the pulmonary vein and ...

...SPECIFICATION A1

BACKGROUND OF THE INVENTION

Field of the Invention.

This invention relates to **methods** and apparatus for the medical treatment of disease of the heart. More particularly, this invention relates to a **method** and apparatus for treating **cardiac arrhythmias**

by **ablating** in a vicinity of pulmonary venous tissue.

#### Description of the Related Art.

Tissue **ablation** from the inner walls of hollow viscera of the body generally, and the vascular **system** in particular, has been found to be useful in the treatment of various medical conditions. Technological developments in intravascular **catheters**, manipulative instruments adapted to intravascular **catheters**, and **catheter** localization **techniques** have especially benefited the field of **cardiology**. Percutaneous transcatheter **ablation** has been used successfully in the treatment of conduction defects and **arrhythmias** of various types. Today, **atrial** tachyarrhythmias are a common application for **ablative** therapy.

Various **ablative** modalities have been employed in the past, such as **ablation** by direct heating. Energy can be conducted to the target tissue using various modalities, such...

...ultrasound, laser, resistive heating, and radiofrequency energy.

One ablative approach is the so-called "maze" **technique**. In general, the maze **procedure** attempts to block abnormal conduction patterns in the left atrium by establishing a maze-like pattern of **linear** lesions in the left atrial wall.

Atrial **arrhythmias** are known to be associated with abnormal electrical activity of tissue foci in the vicinity of the pulmonary veins, especially the superior pulmonary veins. Various **ablative** treatments of such foci have been attempted. For example, the production of linear **atrial** lesions by **radiofrequency** **ablation**, in combination with **ablation** of suspected **arrhythmogenic** foci has been performed using transcatheter **techniques**.

More recently, circumferential **lesions** at or near the ostia of the pulmonary veins have been created to treat **atrial** **arrhythmias**. U.S. Patent Nos. 6,012,457 and 6,024,740, both to Lesh, disclose a radially expandable **ablation** device, which includes a radiofrequency electrode. Using this device, it is proposed to deliver radiofrequency energy to the pulmonary veins in order to establish a circumferential conduction block, thereby **electrically** **isolating** the pulmonary veins from the left atrium.

**Radiofrequency** **ablation** using multiple contiguous circumferential points, guided by electro-anatomical mapping is proposed in the document, Circumferential **Radiofrequency** **Ablation** of Pulmonary Vein Ostia: A New Anatomic Approach for Curing **Atrial** **Fibrillation**, Pappone C, Rosanio S, Oreto G, Tocchi M, Gugliotta F, Vicedomini G, Salvati A, Dicandia...

...2628 (2000). It is emphasized that particular care must be exercised to ensure that the **ablation** sites are indeed contiguous; otherwise irregular electrical activity in the pulmonary vein may continue to contribute to **atrial** **arrhythmia**.

It has also been proposed to produce circumferential **ablative** **lesions** using ultrasound delivered through a balloon. This **technique** is described, for example, in the document, First Human Experience With Pulmonary Vein Isolation Using a Through-the-Balloon Circumferential Ultrasound **Ablation** **System** for Recurrent **Atrial** **Fibrillation**, Natale A, Pisano E, Shewchik J, Bash D, Fanelli R, MD; Potenza D; Santarelli P...

...P; Lesh M, Circulation 102:1879-1882 (2000).

A known drawback in the use of **radio** **frequency** energy for **cardiac** tissue **ablation** is the difficulty in controlling the local heating of

tissue. There are tradeoffs between the clinical desire to create a sufficiently large **lesion** to effectively ablate an abnormal tissue focus, or block an aberrant conduction pattern, and the undesirable effects of excessive local heating. If the radiofrequency device creates too small a **lesion**, then the medical **procedure** could be less effective, or could require too much time. On the other hand, if...

...The use of slower heating provides better control of the ablation, but unduly prolongs the **procedure**.

In consideration of these, and other factors, it is appropriate, in designing a practical radiofrequency...

...withdrawal, and repositioning of the device so as to be able to conveniently produce multiple **lesions** during the same medical **procedure**.

Previous approaches to controlling local heating include the inclusion of thermocouples within the electrode and feedback control, modulation of the radiofrequency signal, local cooling of the **catheter** tip, and fluid assisted **techniques**, for example perfusion of the target tissue during the energy application, using chilled fluids. Typical...

...four to seven radiofrequency applications for completion of the isolation of each pulmonary vein. Other **techniques** utilize a coil within an expandable balloon. Radiofrequency or ultrasound energy from the coil is...

...the balloon together with a conductive fluid, into surrounding tissue.

Publications which describe various medical **techniques** of interest include:

1. Scheinman MM, Morady F. Nonpharmacological Approaches to Atrial **Fibrillation**. Circulation 2001;103:2120-2125.

2. Wang PJ, Homoud MK, Link MS, Estes III NA. Alternate energy sources for **catheter ablation**. Curr Cardiol Rep 1999 Jul;1(2):165-171.

3. Fried NM, Lardo AC, Berger RD, Calkins H, Halperin HR. **Linear lesions** in myocardium created by Nd:YAG laser using diffusing optical fibers: in vitro and in...Devices; by John C. Middleton and Arthur J. Tipton. 1998.

6. Keane D, Ruskin J, **Linear atrial ablation** with a diode laser and fiber optic **catheter**. Circulation 1999; 100:e59-e60.

7. Ware D, et al., Slow intramural heating with diffused laser light: A unique **method** for deep myocardial coagulation. Circulation; March 30, 1999; pp. 1630-1636.

Other medical technologies of...

...a primary object of some aspects of the present invention to provide improved apparatus and **methods** for electrically isolating the pulmonary vein by accomplishing a circumferential conduction block surrounding the pulmonary...

...and other objects of the present invention are attained by a medical device comprising a **catheter** introduction apparatus in combination with a radiofrequency emitter that comprises a radially expandable helical coil, which is fabricated from a shape memory alloy. The distal end of the **catheter** introduction apparatus is placed at a desired location at the ostium of a pulmonary vein. The coil is energized, and an ablation **lesion** is produced, preferably by the transfer of a single application of radiofrequency energy from the...

...helical coil is expanded by joule heating from a radiofrequency generator to conform to the **lumen** of the pulmonary vein and to come into a circumferential contacting relationship therewith.

Alternatively or...

...helical coil is constructed of a biodegradable material, and is left in place following the **ablative procedure**.

The invention provides a **method** for **electrically isolating a cardiac chamber**, including the steps of introducing a coil into a pulmonary vein proximate an ostium...

...to engage the inner wall of the pulmonary vein.

According to another aspect of the **method**, the when heated, coil becomes tapered, such that the proximal segment of the coil is more radially expanded than the distal segment thereof.

In a further aspect of the **method** the coil axially expands when heated.

In yet another aspect of the **method** the shape of the coil is adjusted by differentially heating segments of the coil. Differential...

...the segments of the coil, or by inductive heating.

In still another aspect of the **method** differential heating is achieved by subjecting the coil to a single electromagnetic influence for heating...

...a coolant to selected segments of the coil.

According to still another aspect of the **method**, a width dimension of the ablation region is at least as large as the pitch of the coil.

An additional aspect of the **method** introducing includes transferring the coil into the heart through the interatrial septum, and while transferring...

...ablated to accommodate passage of the coil therethrough.

According to yet another aspect of the **method**, the coil is constructed of a biodegradable material.

In still another aspect of the **method** radiofrequency energy is conducted to the ablation region in a single continuous application.

In another aspect of the **method** the coil is circumferentially engaged by disposing the coil about an anchoring balloon, and inflating...

...radially expand the coil. The anchoring balloon can be bilobate or pyriform when expanded.

The **method** is applicable to hollow viscera other than the heart and the pulmonary veins.

#### BRIEF DESCRIPTION...

...wherein:

Figs. 1A and 1B, collectively referred to herein as Fig. 1, illustrate a therapeutic **catheter** that is constructed and operative in accordance with a preferred embodiment of the invention;

Fig. 2 is an enlarged schematic illustration of the distal end of the **catheter** shown in Fig. 1 with an inflation balloon expanded, and a radiofrequency ablation element in place;

Fig. 3 is a flow chart of a **method** for electrically ...with a preferred embodiment of the invention;

Fig. 4 schematically illustrates certain aspects of a **method** of intracardiac **catheter** access during a first phase of the **method** shown in Fig. 3;

Fig. 5 schematically illustrates certain aspects of a **method** of intracardiac **catheter** access during a second phase of the **method** shown in Fig. 3;

Fig. 6 schematically illustrates certain aspects of a **method** of intracardiac **catheter** access during a third phase of the **method** shown

in Fig. 3;

Fig. 7 is a schematic view of a coil that is...

...is constructed and operative in accordance with a preferred embodiment of the invention. An intravascular **catheter** 10 has a proximal end 12 and a distal end 14. The distal end 14...

...18 are preferably inflatable balloons, made from rubber, polyurethane, or a similar elastic material. The **catheter** 10 has one or more **lumens**, which conduct fluid for inflating and deflating the seals 16, 18. One of the **lumens** terminates in a port 20, and is useful for injection of fluids and withdrawal of blood as may be required during use. Other **lumens** are provided for passage of **guidewires** and instruments therethrough. An inflatable anchoring balloon 22, shown in a deflated condition, is located distal to the seals 16, 18. The **catheter** 10 also has a coaxial **guidewire lumen** 24.

Preferably the active sites to be ablated are identified using the location and mapping **system** disclosed in commonly assigned U.S. Patent No. 5,840,025 and U.S. Patent...

...of U.S. Patent No. 5,840,025, certain components of the location and mapping **system** are incorporated into the distal end 14 of the **catheter** 10, namely a mapping electrode 26 and a transmitting **antenna** 28, which can be a dipole **antenna**. The mapping electrode 26 detects local electrical activity of the heart, and the **antenna** 28 transmits signals to a plurality of receiving **antennae** (not shown) which are placed on the body surface of a patient during use. The...

...end 14 can be radio-opaque, in order to facilitate its localization by conventional radiographic **techniques**, alternatively or in addition to the **system** disclosed in the above-noted U.S. Patent No. 5,840,025.

For the embodiment...

...in U.S. Patent No. 5,391,199 certain components of the location and mapping **system** are incorporated into the distal end 14 of the **catheter** 10, namely the mapping electrode 26 and a location sensor 28, which is a position...

...define a frame of reference in order to track the position and orientation of the **catheter** distal end 14. Thus, based on the electromagnetic fields received at the location sensor 28, the location sensor 28 transmits a location signal to the signal **processor** /control **system** (not shown) by providing at least 5 dimensions of position and orientation information (X, Y...

...end 14 can be radio-opaque, in order to facilitate its localization by conventional radiographic **techniques**, alternatively or in addition to the **system** disclosed in the above-noted U.S. Patent No. 5,391,199.

In embodiments in which the **system** disclosed in the above-noted U.S. Patent Nos. 5,840,025 and 5,391...

...not used, the mapping electrode 26 performs conventional monitoring of local electrical activity, and the **antenna** 28 can be omitted.

Reference is now made to Fig. 2, which is a partially schematic enlarged view of the distal end 14 of the **catheter** 10 shown in Fig. 1. The anchoring balloon 22 is inflated, and preferably has a...by applying voltage. It can be readily formed into a desired shape by well-known **techniques**. The axis of the coil 34 and the axis of the anchoring balloon 22 are both generally aligned, as indicated by a **line** 36. The pitch of the coil 34 is represented by the **linear** distance between the same points on adjacent loops, for example the distance between a point

38 and a point 40 on the **line** 36. The pitch of different segments of the coil 34 may vary.

The coil 34...

...may be desirable to allow the coil 34 to remain in situ following an ablative **procedure**, and because of its helical shape, the coil 34 is adaptable for use as a...

...promotes ease of use, radial expansion and contraction, and withdrawal following completion of the ablative **lesion**.

More generally, use of the coil as described facilitates the creation of a complete **line** of block surrounding the pulmonary vein ostium in a single ablation application. By contrast, some currently available **techniques** require multiple RF ablations, e.g., four to seven ablations, for completion of the isolation of each pulmonary vein. Other **techniques** utilize a coil within an expandable balloon, whereby radiofrequency energy from the coil is passed...

...the balloon, then through the balloon, and only at that point into surrounding tissue. Advantageously, **procedures** performed using the coil provided by this embodiment of the present invention are believed to be simpler, quicker, and more efficient than those which use the **methods** provided by the prior art.

Preferably the coil 34 is securely attached to the anchoring balloon 22 or the distal end 14 of the **catheter** 10, and is removed from the pulmonary vein ostium when the **catheter** 10 is withdrawn at the completion of the **procedure**.

In some embodiments, the coil 34 is made of a biodegradable material, for example polymer...

...It is detachable from the anchoring balloon 22 or the distal end 14 of the **catheter** 10. In these embodiments the coil 34 remains firmly engaged circumferentially with the inner lining...

...and shape memory. The coil 34 is allowed to remain in situ following the ablation **procedure**, and it is eventually resorbed. In such embodiments, the continued stenting of the pulmonary vein...

...daunorubicin, doxorubicin and idarubicin), anthracyclines, mitoxantrone, bleomycins, plicamycin (mithramycin) and mitomycin, enzymes (L-asparaginase which **systemically** metabolizes L-asparagine and deprives cells which do not have the capacity to synthesize their... inhibitors.

Reference is now made to Fig. 3, which is a flow chart of a **method** for electrically isolating pulmonary veins, which is operative in accordance with a preferred embodiment of...

...of various monitoring and grounding leads, as may be required for electrophysiological monitoring of the **procedure**, and for the operation of the above-noted location and mapping **system**.

Next, at step 48, a series of events begins, ultimately leading to the positioning of the **catheter** 10 and the coil 34 at the ostium of a pulmonary vein. Step 48 is conventional. In a preferred approach, the venous **system** is accessed using the well-known Seldinger **technique**, in which an introducer sheath is positioned in a peripheral vein, typically a femoral vein...

...if necessary. The Brockenbrough needle is withdrawn, and the guiding sheath placed in the left **atrium**. Alternatively, the **ablation catheter** is energized as it contacts the interatrial septum, usually at the fossa ovalis. **Ablation** of septal tissue eases the passage of the

**catheter** through the septum, reduces the amount of hardware used, and shortens the **procedure**, as it is not necessary to pass a dilator through the fossa ovalis. It is...

...the left atrium via the superior vena cava, or to use a retrograde intra-arterial **technique**.

Next, in step 50 a **guidewire** is advanced through the guiding sheath, through the left atrial chamber, into a pulmonary vein...

...the inferior pulmonary veins. Thereafter the inferior pulmonary veins may be isolated. Typically, an ablation **procedure** involves the isolation of all four pulmonary veins.

Reference is now made to Fig. 4, which schematically illustrates certain aspects of the **method** of electrical pulmonary vein isolation in accordance with a preferred embodiment of the invention. The...

...has been positioned, on the left atrial side of an interatrial septum 68. A conventional **guidewire** 70 extends through the **lumen** of the guiding sheath 64, into the **lumen** of the left superior pulmonary vein 56. It will be understood that while the **guidewire** 70 is shown in relation to the left superior pulmonary vein 56, the **technique** is equally applicable to the other pulmonary veins.

Referring again to Fig. 3, at step 72, the guiding sheath is withdrawn, and an ablation **catheter** is slidably tracked over the **guidewire**, using the **guidewire lumen** of the **catheter**. The **catheter** is advanced into the left atrium. While maneuvering the **catheter** in the heart, its position is preferably monitored by the location and mapping **system** disclosed in the above-noted U.S. Patent No. 5,840,025, or alternatively by conventional imaging modalities. The anchoring balloon of the **catheter** is deflated during the positioning maneuver. The tip of the **catheter** is located at the ostium of a pulmonary vein, such that a first segment of the **catheter**'s anchoring balloon, which is substantially the balloon's proximal third, is disposed in the...

...second segment of the anchoring balloon, composed of its remaining distal portion, lies within the **lumen** of the pulmonary vein.

Reference is now made to Fig. 5, which schematically illustrates certain aspects of the **method** of electrical pulmonary vein isolation in accordance with a preferred embodiment of the invention. The...

...corresponding structures in Fig. 4 have been given like reference numerals. The shaft of the **catheter** 10 extends through the interatrial septum 68. The anchoring balloon 22 and the coil 34...

...the left superior pulmonary vein 56, such that the coil 34 is movable within the **lumen**.

Referring again to Fig. 3, at step 74, the coil 34 is caused to expand ...resistively heating the coil. The radially expanded coil engages the pulmonary vein in a continuous **line** that runs circumferentially about the pulmonary vein proximate its ostium, and the coil is seated...

...as a stent for the pulmonary vein. Perfusion of the area through one of the **catheter** ports may be employed during step 74 to minimize stasis of blood in the region...

...tissue.

Reference is now made to Fig. 6, which schematically illustrates certain aspects of the **method** of electrical pulmonary vein isolation in accordance with a preferred embodiment of the invention. The...

2 ...56 are illustrated, it being understood that the contact actually occurs



in a continuous circumferential **line** . The pitch-to-radius ratio of the coil 34 is selected such that a circumferential ablation **lesion** produced in the target tissue bridges the distance between two adjacent loops, for example, loops...

...continuous electrophysiological monitoring, an end point being reached when conduction block is confirmed across the **line** of ablation.

Upon completion of the ablation, in step 84 the anchoring balloon is deflated...

...accomplished by resistive heating, exploiting the shape memory of the coil. The tip of the **catheter** is withdrawn into the left atrial chamber. The **guidewire** is also withdrawn from the pulmonary vein.

Next, at decision step 86, a test is...

...coil is separated from the anchoring balloon and left in place as a stent. The **procedure** thereupon terminates in either case.

Alternate embodiments.

Reference is now made to Fig. 7, which...

...apart. However, in practice they generally are not. The coil 92 is placed on a **catheter** and introduced as disclosed hereinabove. It is then heated to accomplish shape adjustment. One or...

...having a plurality of ferrite cores, to differentially heat the segments 96, 98. An external **loop antenna** with a radius of 25-30 cm, having 10-20 windings, is powered by a...measuring temperature and local circuit impedance. The information obtained from the sensors 146, 148 is **processed** using known digital processing **techniques** . The coil 92 acts as an **antenna** , schematically referenced as **antenna** 150, for transmitting a signal from the ASIC circuit 144 to a control **processor** 152.

It will be appreciated by persons skilled in the art that the present invention...

#### ...CLAIMS A1

1. A **system** for electrically isolating a cardiac chamber, comprising:  
means for introducing a coil into a pulmonary vein proximate an ostium of...
- ...of contact, to ablate tissue in an ablation region of said pulmonary vein.
2. The **system** according to claim 1, wherein a width dimension of said ablation region is at least as large as a pitch of said coil.
3. The **system** according to claim 1, wherein:  
said means for introducing is adapted to transfer said coil...
- ...being transferred through said interatrial septum, to ablate tissue of said interatrial septum.
4. The **system** according to claim 3, wherein said means for conducting radiofrequency energy is adapted to conduct...
- ...interatrial septum has been ablated to accommodate a passage of said coil therethrough.
5. A **system** for ablating tissue, comprising:  
means for providing a coil that is constructed of a shape...
- ...of contact, while maintaining said circumferential region of contact, to ablate tissue therein.

6. The **system** according to claim 1 or claim 5, wherein said means for engaging is adapted to circumferentially engage said coil by radially expanding said coil.
7. The **system** according to claim 6, wherein said coil is constructed of a shape memory alloy.
8. The **system** according to claim 6, wherein means for providing said coil is adapted to form zigzag folds in a plurality of windings thereof.
9. The **system** according to claim 6, wherein a proximal segment of said coil is more radially expandable than a distal segment thereof.
10. The **system** according to claim 7, further comprising means for varying a temperature of said coil to alter a configuration thereof.
11. The **system** according to claim 10, which is adapted such that, while said means for varying said temperature is operating, said coil radially expands responsive to a shape memory thereof.
12. The **system** according to claim 7, wherein said means for radially expanding said coil is adapted to cause tapering of said coil.
13. The **system** according to claim 7, wherein said means for circumferentially engaging said coil is adapted to cause axial expansion of said coil.
14. The **system** according to claim 13, wherein including means for differentially heating segments of said coil for expanding said coil.
15. The **system** according to claim 14, wherein said means for differentially heating is adapted to pass different amounts of current through different ones of said segments of said coil.
16. The **system** according to claim 14, wherein said means for differentially heating is an inductive heating means.
17. The **system** according to claim 14, wherein said means for differentially heating is adapted to:  
subject said...
- ...and  
conduct a coolant to selected ones of said segments of said coil.
18. The **system** according to claim 1 or claim 5, wherein said coil is constructed of a biodegradable material.
19. The **system** according to claim 1 or claim 5, wherein said means for conducting radiofrequency energy is adapted to perform in a single continuous application.
20. The **system** according to claim 1 or claim 5, wherein said means for circumferentially engaging said coil...
- ...an anchoring balloon; and  
inflate said anchoring balloon to radially expand said coil.
21. The **system** according to claim 20, wherein following operation of said means for circumferentially engaging to inflate...
- ...of said anchoring balloon has a larger diameter than a distal segment thereof.
22. The **system** according to claim 21, wherein said anchoring balloon is bilobate or pyriform.

22/3,K/9 (Item 9 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
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01403425

**Surgical microwave ablation assembly**

**Chirurgische Mikrowellenablationsvorrichtung**

**Dispositif chirurgical d'ablation par micro-ondes**

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LU; MC; NL; PT; SE; TR

EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

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SPEC A	(English)	200211	17099
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Total word count - document B			0
Total word count - documents A + B			19971

INTERNATIONAL PATENT CLASS: A61B-018/14 ...

... A61B-018/18 ...

... A61B-017/20

...SPECIFICATION A2

Background of the Invention

The present invention relates to apparatus and **methods** for ablating biological tissues. More particularly, the present invention relates to improved ablation devices that...

...have been introduced and employed to various degrees to ablate biological tissues. In some ablation **procedures**, however, the ablation of the targeted tissues may be difficult because of their location or the presence of physiological obstacle. For example, in some coronary applications where the **ablation** lines are done epicardially, the **epicardium** may be covered by layers of fat that can prohibit the **lesion** formation in the myocardial tissue.

Catheter devices are commonly used to perform the **ablation procedure**. They are generally inserted into a major vein or artery or through a

bodily cavity such as the mouth, urethra, or rectum. These **catheters** are then guided to a targeted location in the body (e.g., organ) by manipulating the **catheter** from the insertion point or the natural body's orifice. By way of example, in coronary applications, a **catheter** is typically inserted tranvenously in the femoral vein and guided to a cardiac chamber to ablate **myocardial** tissues. Although catheters work well for a number of applications, in many applications it would be desirable to provide an **ablation** assembly that can be used to position an ablation device during a surgical **procedure**.

#### Summary of the Invention

To achieve the foregoing and other objects of the invention, **methods** and devices pertaining to the ablation of tissues inside the cavity of an organ are...

...strong to cause tissue ablation, and a probe, which has a needle shaft with a **lumen** extending therethrough. The needle shaft also has a proximal access end and a distal penetration...

...is adapted to penetrate through a wall of an organ to an organ cavity. The **lumen** is arranged for slidably carrying the ablation tool from an undeployed position, which places the distal portion of the ablation tool inside the **lumen** of the needle shaft, to a deployed position, which places the distal portion of the...

...The invention relates, in another embodiment, to an ablation assembly that includes a probe, an **antenna** and a transmission **line**. The probe is adapted to be inserted into a body cavity and to penetrate an organ within the body cavity. The probe also has a longitudinal axis. The **antenna** is carried by the probe for insertion into a cavity within the organ, and the transmission **line** is carried by the probe for delivering electromagnetic energy to the **antenna**. Furthermore, the **antenna** and transmission **line** are arranged such that when the **antenna** is deployed into the organ cavity, the **antenna** lies at an angle relative to the longitudinal axis of the probe. In some embodiments, when the **antenna** is deployed into the organ cavity, the **antenna** lies proximate and substantially parallel to the inner wall of the organ.

The invention relates, in another embodiment, to a microwave ablation assembly that includes an elongated probe, a transmission **line** and **antenna** device. The probe has a penetration end adapted to penetrate into an organ and an...

...insert passage extending therethrough from the access end to the penetration end thereof. The transmission **line** is arranged for delivering microwave energy, and has a proximal end coupled to a microwave energy source. The **antenna** device is distally coupled to the transmission **line**, and is arranged for radiating a microwave field sufficiently strong to cause tissue ablation. The **antenna** device further includes an **antenna** and a dielectric material medium disposed around the **antenna**. Furthermore, the **antenna** device and at least a portion of the transmission **line** are each dimensioned for sliding receipt through the insert passage of the elongated probe; while the elongated probe is positioned in the organ, to a position advancing the **antenna** device past the penetration end of the probe and at an angle relative to the longitudinal axis of the probe.

In some embodiments, the transmission **line** is a **coaxial cable** that includes an inner conductor, an outer conductor, and a dielectric medium disposed between the...the ablation assembly further includes a ground plane configured for coupling electromagnetic energy between the **antenna** and the ground plane. The ground plane is generally coupled to

the outer conductor of the transmission line and is positioned on the transmission line such that when the antenna is advanced into the organ cavity proximate the inner wall of the organ, the ground...

...proximate the outer wall of the organ.

The invention relates, in another embodiment, to a method for ablating an inner wall of an organ. The method includes providing a surgical device that includes a probe and an ablation tool. The probe...

...energy, is carried by the probe for insertion into a cavity within the organ. The method further includes introducing the surgical device into a body cavity. The method additionally includes penetrating a wall of the organ with the probe. The method also includes advancing the probe through the wall of the organ and into an interior chamber thereof. The method further includes deploying the distal portion of the ablation tool inside the interior chamber of...

...organ at an angle relative to the longitudinal axis of the probe, wherein the distal antenna is positioned proximate an inner wall of the organ. Moreover, the method includes delivering ablative energy that is sufficiently strong to cause tissue ablation.

In most embodiments...

...being ablated, is the heart. As such, the ablation assembly may be used to create lesions along the inner wall of the heart. By way of example, these lesions may be used treat atrial fibrillation, typical atrial flutter or atypical atrial flutter.

The invention relates, in another embodiment, to an ablation assembly that includes a needle antenna and a transmission line. Both the needle antenna and the transmission line are adapted to be inserted into a body cavity. The transmission line is arranged for delivering electromagnetic energy to the needle antenna, and includes a longitudinal axis. The needle antenna is arranged for transmitting electromagnetic energy that is sufficiently strong to cause tissue ablation. The needle antenna is also includes a penetration end adapted to penetrate an organ within the body cavity such that the needle antenna can be advanced through a wall of the organ into a cavity within the organ. Furthermore, at least one of the needle antenna or the transmission line is bent at an angle relative to the longitudinal axis of the transmission line so that the needle antenna can be positioned proximate an inner wall of the organ.

The invention relates, in another embodiment, to a method for ablating an inner wall of an organ. The method includes providing a surgical device that has a needle antenna distally coupled to a transmission line. The transmission line has a longitudinal axis, and the needle antenna has a distal penetration end that is adapted to penetrate through a wall of an organ. The needle antenna is also adapted for delivering electromagnetic energy. Furthermore, at least one of the needle antenna or the transmission line is bent at an angle relative to the longitudinal axis of the transmission line. The method further includes introducing the surgical device into a body cavity. The method additionally includes penetrating a wall of the organ with the distal penetration end of the needle antenna. The method also includes advancing the needle antenna through the wall of the organ and into an interior chamber thereof. The method further includes positioning the needle antenna inside the interior chamber of the organ such that the needle antenna is proximate an inner wall of the organ. Moreover, the method includes radiating electromagnetic energy that is sufficiently strong to cause tissue ablation.

Brief Description of...

...present invention.

Fig. 2A is a top plan view of an ablation tool including an **antenna** device and a transmission **line** , in accordance with one embodiment of the present invention.

Fig. 2B is a side elevation view, in cross section, of the **antenna** device of Fig. 2A, in accordance with one embodiment of the present invention.

Fig. 2C is a front elevation view of the **antenna** device taken substantially along the plane of the **line** 2-2' in Fig. 2B, in accordance with one embodiment of the present invention.

Fig. 2D is a perspective view of the **antenna** device of Fig. 2A, in accordance with one embodiment of the present invention.

Figs. 3A...

...Fig. 6A is a side elevation view, in cross section, of another embodiment of the **antenna** device.

Fig. 6B is a front elevation view of the **antenna** device taken substantially along the plane of the **line** 6-6' in Fig. 6A, in accordance with one embodiment of the present invention.

Fig. 7 is a perspective view of another embodiment of the **antenna** device.

Fig. 8 is a perspective view of another embodiment of the **antenna** device.

Fig. 9A is a side cross sectional view of the **antenna** device of Fig. 2 while it is generating a concentrated electromagnetic field, in accordance with...

...embodiment of the present invention.

Fig. 9B is a front cross sectional view of the **antenna** device of Fig. 2 while it is generating a concentrated electromagnetic field, in accordance with...

...of the present invention.

Fig. 10 is a perspective view of another embodiment of the **antenna** device.

Fig. 11 is a perspective view of another embodiment of the **antenna** device.

Figs. 12A & 12B are side elevation views, in cross section, of an ablation assembly...

...one embodiment of the present invention.

Fig. 17 is a side elevation view showing a **cardiac** procedure using the **ablation** assembly of Figs. 1-3, in accordance with one embodiment of the present invention.

Fig. 18 is a top plan view of an ablation assembly having a needle **antenna** , in accordance with one embodiment of the present invention.

Fig. 19 is a side elevation...

...present invention.

Fig. 21 is a side elevation view, in cross section, of a needle **antenna** , in accordance with one embodiment of the present invention.

Fig. 22 is a side elevation view, in cross section, of a needle **antenna** , in accordance with one embodiment of the present invention.

Fig. 23 is a side elevation view, in cross section, of a needle **antenna** , in accordance with one embodiment of the present invention.

Fig. 24 is a side elevation view, in cross section, of a needle **antenna** , in accordance with one embodiment of the present invention.

Figs. 25A & 25B are side elevation views of a needle **antenna** having

acute and obtuse angular positions, respectively, in accordance with one embodiment of the present invention.

Fig. 26 is a perspective view of a needle **antenna** having a gripping block, in accordance with one embodiment of the present invention.

Figs. 27A is a perspective view of a needle **antenna**, in accordance with one embodiment of the present invention.

Figs. 27B is a side elevation view of the needle **antenna** of Fig 27A, in accordance with one embodiment of the present invention.

Figs. 27C is a side elevation view of the needle **antenna** of Fig. 27A after penetrating an organ wall (in cross section), in accordance with one...

- ...be practiced without some or all of these specific details. In other instances, well known **process** steps have not been described in detail in order not to unnecessarily obscure the present...
- ...duct). More specifically, the present invention provides an ablation assembly that is capable of producing **lesions** along an interior wall of an organ. The ablation assembly generally includes an ablative energy...
- ...ablation assembly includes a probe and an ablation tool. The ablation tool, which includes an **antenna** and a transmission **line** coupled to the **antenna**, is adapted to be carried by the probe for insertion within a cavity inside the organ. The transmission **line** is arranged for delivering electromagnetic energy to the **antenna**. The probe is adapted to be inserted into a body cavity and to penetrate an organ within the body cavity. Furthermore, the ablation assembly is arranged so that when the **antenna** is deployed into the organ cavity, the **antenna** lies at an angle relative to the longitudinal axis of the probe. In some embodiments, upon deployment, the **antenna** is configured to assume a predetermined position that substantially matches the shape and/or angular...organ 18 within a body cavity 20. The probe 12 also has a longitudinally extending **lumen** 22 that is sized suitably for receiving the ablation tool 24 therethrough. The ablation tool 24 includes a transmission **line** 28 that carries an **antenna** device 30 at its distal end. The **antenna** device 30 is designed to generate an electromagnetic field sufficiently strong to cause tissue ablation. A proximal end 42 of the transmission **line** 28 is coupled to an energy source (not shown).  
The **antenna** device 30 and the transmission **line** 28 are sized such that they are slidable through the **lumen** 22 while the elongated probe 12 is positioned in a wall 35 of the organ...
- ...As such, the ablation tool 24 may be advanced within the probe 12 until the **antenna** device 30 is moved into a cavity within the organ 18 at a position beyond...
- ...that when it is extended beyond the penetration end 16 of the probe 12, the **antenna** 30 lies at an angle 38 relative to the longitudinal axis 40 of the probe...
- ...of the probe). In many embodiments, the angle 38 is arranged such that when the **antenna** device 30 is deployed into the organ cavity, the **antenna** device 30 assumes a predetermined angular position that matches the shape and/or angular position...
- ...the wall to be ablated. By way of example, an angular position that places the **antenna** device substantially parallel to the cavity wall may be used.  
Accordingly, an ablation assembly is provided which utilizes a thin, elongated probe as a deployment mechanism to position an **antenna** device

within the organ targeted for ablation. Once the probe is positioned in a wall of the organ, the **antenna** device and the transmission **line** are inserted through the passage of the probe as a unit until the **antenna** device is positioned inside the cavity of the organ. Subsequently, an electromagnetic field is emitted from the **antenna** device that is sufficiently strong to cause tissue ablation. This arrangement is especially beneficial when...

...epicardial surface (e.g., outer wall) of the heart. Additionally, the angular component of the **ablation** assembly allows precise positioning and placement of the **antenna** device at specific locations within the cavity of a bodily organ. As a result, the...

...or a beveled point chamfered needle both of which form a sharp cutting edge. The **lumen** 22 extends longitudinally through the needle shaft 44, and includes a proximal access opening 46...

...end of the needle shaft 44 to help facilitate the insertion and extraction of the **antenna** device 30 into and out of the proximal access opening 46 of the **lumen** 22.

In general, the needle shaft 44 is a thin walled rigid **tube** having an outer diameter of about less than about 3 mm and an inner diameter...

...the range of between about 0.003 inches to about 0.007 inches, and a **lumen** diameter (inner diameter) in the range of about 0.040 inch to about 0.060...

...used. In the embodiment shown, the wall thickness is about 0.005 inches and the **lumen** diameter is about 0.050 inches. This relatively small diameter size is particularly suitable for...

...placed at the proper selected depth (such as that shown in Figs. 3A & 3B), the **antenna** device 30 may be advanced into the organ cavity.

In some embodiments, the probe 12 and the ablation tool 24 are formed as an integral unit, wherein the **antenna** device 30 is ...to the ablation tool 24, may be used to control the sliding movement of the **antenna** tool 24 through the probe 12. As such, the first predetermined position is configured to place the **antenna** device 30 in an un-advanced position (as shown in Fig. 3A) and the second predetermined position is configured to place the **antenna** device 30 in a deployed position (as shown in Fig. 3B). In other embodiments, the...

...the organ 18. After ablation tool 24 has been inserted into the probe 12, the **antenna** device 30 can be advanced from the un-advanced position (as shown in Fig. 3A...

...During deployment, the ablation tool 24 is moved through the handle 50 and through the **lumen** 22. As best viewed in Figs. 3A & 3B the **antenna** device 30 and the associated transmission **line** 28 are advanced longitudinally through the **lumen** 22 of the needle shaft 44 to the distal penetration end 16 thereof. Upon subsequent advancement, the **antenna** device 30 may be manipulated to extend through the penetration opening 47 of the insert passage 22 and into the cavity of the organ 18. Such advancement allows the **antenna** device 30 to assume a predetermined position having an angle 38 relative to the longitudinal...

...18, and substantially parallel to the tissue targeted for ablation thereof. In one embodiment, the **antenna** device is arranged to move into the angled position during advancement of the **antenna** tool through the probe. In another embodiment, the **antenna** device is arranged to move .



into the angled position after advancement of the **antenna** tool through the probe. Deployment **techniques** will be discussed in greater detail below.

As shown in Figs. 3A & 3B, the probe 12 is perpendicularly penetrating the organ 18, and the **antenna** device 30 is positioned about 90 degrees from the longitudinal axis 40 of the probe...

...and/or angular position of the wall to be ablated. By way of example, an **antenna** device position having an angle in the range of between about 45 degrees to about 135 degrees may be used. To illustrate this, Fig. 4A shows the **antenna** device 30 in an acute angular position having an angle 38 of about 60 degrees relative to the longitudinal axis 40, and Fig. 4B shows the **antenna** device 30 in an obtuse angular position having an angle 38 of about 120 degrees...

...to the longitudinal axis 40. These angular positions are important parameters for ensuring that the **antenna** device is properly positioned in a direction towards the tissue targeted for ablation. Furthermore, although...

...other angles may be used.

Several embodiments associated with angled positioning and deployment of the **antenna** device will now be described in detail. It should be appreciated, however, that the present...

...assembly may include a biasing member that is specifically formed and shaped for urging the **antenna** device to a predetermined bent position. That is, the biasing member has a predetermined shape that corresponds to the angled position of the **antenna** device. As soon as the **antenna** device is advanced into the organ cavity the biasing member moves to assume its predetermined shape and thus the **antenna** device moves to the predetermined bent position. The biasing member generally consists of one or...

...like strips or rods that extend through the ablation arrangement in the area of the **antenna** device. The strips or rods may be arranged to have a circular, rectangular, or other...

...that typically exhibits superb flexibility and unusually precise directional preference when bending. Accordingly, when the **antenna** device is positioned within the cavity of an organ, the nitinol strip enables the **antenna** device to conform to the inner wall of the organ. Similarly, when the **antenna** device is withdrawn from the organ, the **Nitinol** strip facilitates straightening to allow removal through the probe.

In another embodiment, the assembly may include a steering **system** for bending the **antenna** device to a predetermined bent position. The steering **system** generally includes one or more wires that extend through the ablation arrangement. The wires are used to pull the **antenna** device from an unbent position to a bent position causing controlled, predetermined bending at the **antenna** device. The pull wires are generally fastened to anchors, which are disposed (attached to) at the proximal end of the **antenna** device. In this type of arrangement, a steering element, located on the handle 50, may...the needle shaft of the probe can be pre-bent or curved to direct the **antenna** device to its advanced position. Referring to Fig. 5, the needle shaft 44 of the probe 12 includes a curved section 55 which redirects the position of the **antenna** device 30 in a manner skewed from the axis 40 of the proximal end 14 of the probe 12. As the distal end of the **antenna** device 30 contacts the curved wall 55 of the insert passage, the **antenna** device 30 is urged toward the distal penetration opening 47 and into the cavity

of...

...to Figs. 2 & 3, the ablation tool 24 is illustrated having an elongated flexible transmission line 28 and an antenna device 30 coupled to the distal end of the transmission line 28. The transmission line 28 is adapted for insertion into the probe 12 and is arranged for actuating and/or powering the antenna device 30. In microwave devices, a coaxial transmission line is typically used, and therefore, the transmission line 28 includes an inner conductor 31, an outer conductor 32, and a dielectric material 33...

...the inner and outer conductors 31, 32. Furthermore, at the proximal end of the transmission line 28 is an electrical connector 42 adapted to electrically couple the transmission line 28, and therefore the antenna device 30, to the energy source (not shown). The transmission line 28 may also include a flexible outer tubing (not shown) to add rigidity and to provide protection to the outer conductor 32. By way of example, the flexible outer tubing may be made of any suitable material such as medical grade polyolefins, fluoropolymers, or polyvinylidene fluoride.

As shown in Figs. 2B-D, the antenna device 30, which is also adapted for insertion into the probe 12, generally includes an antenna wire 36 having a proximal end that is coupled directly or indirectly to the inner conductor 31 of the transmission line 28. A direct connection between the antenna wire 36 and the inner conductor 31 may be made in any suitable manner such...

...in more detail below, in some implementations, it may be desirable to indirectly couple the antenna to the inner conductor through a passive component in order to provide better impedance matching between the antenna device and the transmission line.

In another embodiment, the antenna device 30 can be integrally formed from the transmission line 28 itself. This is typically more difficult from a manufacturing standpoint but has the advantage of forming a more rugged connection between the antenna device and the transmission line. This design is generally formed by removing the outer conductor 32 along a portion of the coaxial transmission line 28. This exposed portion of the dielectric material medium 33 and the inner conductor 31 embedded therein define the antenna device 30 which enables the electromagnetic field to be radiated substantially radially perpendicular to the inner conductor 31. In this type of antenna arrangement, the electrical impedance between the antenna device 30 and the transmission line 28 are substantially the same. As a result, the reflected power caused by the low impedance mismatch is also substantially small which optimizes the energy coupling between the antenna and the targeted tissues.

The antenna wire 36 is formed from a conductive material. By way of example, spring steel, beryllium copper, or silver plated copper may be used. Further, the diameter of the antenna wire 36 may vary to some extent based on the particular application of the ablation...

...type of material chosen. By way of example, in coronary applications using a monopole type antenna, wire diameters between about 0.005 inches to about 0.020 inches work well. In the illustrated embodiment, the diameter of the antenna is about 0.013 inches.

In an alternate embodiment, the antenna wire 36 can be formed from a shape memory metal such as NiTi (Nitinol). As mentioned, Nitinol is a super elastic material that typically exhibits superb flexibility and unusually precise directional preference when bending. Accordingly, when

the **antenna** device 30 is positioned within the cavity of an organ, the **antenna** wire 36 enables the **antenna** device 30 to conform to the inner wall of the organ. Similarly, when the **antenna** device 30 is withdrawn from the organ, the **antenna** wire 36 facilitates straightening to allow removal through the probe 12. It should be noted...

...energy generated by the ablation instrument will be roughly consistent with the length of the **antenna** device 30. As a consequence, ablation devices having specified ablation characteristics can be fabricated by building ablation devices with different length **antennas**. By way of example, in coronary applications, an **antenna** length between about 20 mm and about 50 mm and more particularly about 30 mm a measuring tool that is arranged to measure the ablative **lesion** distance needed for a particular **procedure**. According to the measurements, the length of the **antenna** device can be selected. For instance, in some coronary applications, the tool may be used to measure the distance between the mitral valve and the pulmonary veins.

As shown, the **antenna** wire 36 is a monopole formed by a longitudinal wire that extends distally from the inner conductor 31. However, it should be appreciated that a wide variety of other **antenna** geometries may be used as well. By way of example, nonuniform cross-section monopole, helical coils, flat printed circuit **antennas** and the like also work well. Additionally, it should be understood that longitudinally extending **antennas** are not a requirement and that other shapes and configurations may be used. For example, the **antenna** may be configured to conform to the shape of the tissue to be ablated or to a shape of a predetermined ablative pattern for creating shaped **lesions**.

Furthermore, the **antenna** wire 36 is generally encapsulated by an **antenna** enclosure 37. The **antenna** enclosure 37 is typically used to obtain a smooth radiation pattern along the **antenna** device 30, and to remove the high electromagnetic field concentration present when an exposed part of the **antenna** wire is in direct contact with the tissue to be ablated. A high field concentration can create a high surface temperature on the tissue to **ablate** which is not desirable, especially for **cardiac** applications. The **antenna** enclosure 37 may be made of any suitable dielectric material with low water absorption and...

...detail below, in some implementations, it may be desirable to adjust the thickness of the **antenna** enclosure 37 in order to provide better impedance matching between the **antenna** device 30 and the tissue targeted for ablation. Although exposing the **antenna** wire is not typically done because of the high field concentration, it should be noted that the dielectric material forming the **antenna** enclosure 37 can be removed to form an exposed metallic **antenna**.

As shown in Fig. 3B, the outer conductor 32 is arranged to have a distal...

...39 that is exposed, beyond the penetration end 16 of the probe 12, when the **antenna** device 30 is in its advanced position. While not wishing to be bound by theory it is generally believed that the radiated field tends to be more confined along the **antenna** device 30 when the distal end of the outer conductor 32 is extended in the...

...arrangement can be made with or without an exposed outer conductor.

In one embodiment, the **antenna** device and the outer conductor are covered by a layer of dielectric. This layer of...

...ablation tool 24 includes a protective sheath 45 that surrounds the outer periphery of the **antenna** device 30 and a portion of the outer conductor 32 of the transmission line 28. More specifically, the

protective sheath 45 is arranged to cover at least a portion of the exposed distal portion 39 of the outer conductor 32 and the **antenna** enclosure 37. As shown, the protective sheath may also cover the distal end of the **antenna** enclosure 37. By way of example, the protective sheath may be formed from any suitable...

...band).

A frequent concern in the management of microwave energy is impedance matching of the **antenna** and the various transmission **line** components with that of the power source. An impedance mismatch will cause the reflection of...

...reduction of the overall efficiency. It is desirable to match the impedance of the transmission **line** 28 and the **antenna** device 30 with the impedance of the generator, which is typically fifty ohms.

The transmission **line** 28 is therefore provided by a conventional fifty ohm coaxial design suitable for the transmission...

...of about 400 to about 6000 megahertz. As shown in Fig. 2B, the coaxial transmission **line** 28 includes an inner conductor 31 and a concentric ...must be carefully selected. Each of these variables, together with other factors related to the **antenna** device, may be used to adjust the impedance and energy transmission characteristics of the **antenna** device. Such preferable dielectric materials include air expanded TEFLON(TM), while the inner and outer conductors are composed of silver or copper. The impedance of the transmission **line** may be determined by the equation: where "b" is the diameter of the dielectric material...

...characteristic impedance other than fifty ohms can also be used to design the microwave ablation **system**. Also, in order to obtain good mechanical characteristics of the **coaxial cable** assembly, it is important to consider the hardness or malleability of the selected material.

As it was explained earlier, it is also important to match the impedance of the **antenna** with the impedance of the transmission **line**. As is well known to those skilled in the art, if the impedance is not matched to the transmission **line**, the microwave power is reflected back to the generator and the overall radiation efficiency tends...

...performance. Several embodiments associated with tuning (e.g., improving or increasing the radiation efficiency) the **antenna** device will now be described in detail.

In one embodiment, an impedance matching device is provided to facilitate impedance matching between the **antenna** device and the transmission **line**. The impedance matching device is generally disposed proximate the junction between the **antenna** and the transmission **line**. For the most part, the impedance matching device is configured to place the **antenna** structure in resonance to minimize the reflected power, and thus increase the radiation efficiency of the **antenna** structure. In one implementation, the impedance matching device is determined by using a Smith Abacus Model. The impedance matching device may be determined by measuring the impedance of the **antenna** with a network analyzer, analyzing the measured value with a Smith Abacus Chart, and selecting...

...be any combination of serial or parallel capacitor, resistor, inductor, stub tuner or stub transmission **line**. An example of the Smith Abacus Model is described in Reference: David K. Cheng, "Field...

...which is incorporated herein by reference.

In another embodiment, as shown in Fig. 7, the **antenna** device 30 includes a tuning stub 63 for improving the radiation efficiency of the

**antenna** device 30. The tuning stub 63 is a circumferentially segmented section that extends distally from...

...32. As shown, the tuning stub 63 is generally positioned on one side of the **antenna** device 30, and more particularly to the side which is closest to the tissue targeted...

...component side). The tuning stub 63 is also arranged to partially cover or surround the **antenna** enclosure 37. By way of example, the tuning stub 63 may cover between about 25 % to about 50 % of the perimeter of the **antenna** enclosure 37. Furthermore, the length L of the tuning stub 63 may be adjusted to further improve the radiation efficiency of the **antenna** device 30. For example, by increasing the length L, less power is reflected at the entrance of the **antenna** device 30 and the radiation efficiency of the **system** is increased. The radiation efficiency of the **antenna** device 30 is maximized when the resonance frequency is the same as the electromagnetic signal...

...generator (2.45 GHz for example).

In another embodiment, as shown in Fig. 8, the **antenna** device 30 includes a pair of director rods 65 for improving the radiation efficiency of the **antenna** device 30. As shown, the director rods 65 are generally positioned on one side of the **antenna** device 30, and more particularly to the side which is closest to the tissue targeted...

...g., angular component side). The director rods 65 are disposed on the periphery of the **antenna** enclosure 37 and may be positioned anywhere along the length of the **antenna** device 30. By way of example, one of the director rods 65 may be positioned proximate the distal end of the **antenna** device 30, while the other director rod 65 may be positioned proximate the proximal end of the **antenna** device 30. The position of the director rods may be adjusted to further improve the radiation efficiency of the **antenna** device 30. The director rods are generally formed from a suitable metallic material such as...

...the director rods 65 may be adjusted to further improve the radiation efficiency of the **antenna** device 30. It should be appreciated that a pair of rods is not a limitation...

...pair rods may be used.

One particular advantage of using microwave energy is that the **antenna** device does not have to be in contact with targeted tissue in order to ablate the tissue. This concept is especially valid for **cardiac ablation**. For example, when a **microwave** antenna is located in the **atrium**, the radiated electromagnetic field does not see an impedance change between the blood and the...

...these two media are similar). As a result, almost no reflection occurs at the blood- **myocardium** interface and a significant part of the energy will penetrate in the tissue to produce the **ablation**. In addition, the circulating blood between the **antenna** device and the tissue to be ablated helps to cool down the tissue surface. As such, the **technique** is potentially safer since it is less prone to create coagulation and/or carbonization. By...

...certain advantages it should be noted that this is not a limitation and that the **antenna** device, and more particularly the **antenna** enclosure, may be positioned in direct contact with the tissue to ablate.

Furthermore, as is...

...to those skilled in the art, it is more difficult to ablate tissues when

the **antenna** device is surrounded by air. That is, there is a strong difference in the physical properties (the complex permittivity) between tissue and air. Therefore, in one embodiment, when the **antenna** device is not directly touching the tissue to be ablated, the surrounding cavity is filled...

...distilled water may be used.

In some embodiments, as shown in Figs. 9A & 9B, the **antenna** device 30 is adapted to deliver electromagnetic energy (e.g., microwave) in directions extending substantially radially perpendicularly from the longitudinal axis 51 of the **antenna** wire 36 and through the **antenna** enclosure 37. That is, the **antenna** device 30 generally produces a radial isotropic radiation pattern 41 wherein the generated energy is...

...distributed around its volume. By way of example, the radiation pattern 41 generated by the **antenna** device 30 generally has an ellipsoidal shape along the length of the **antenna** device 30 (as shown in Fig. 9A), and a circular shape around its width (as...

...should be appreciated, however, that other ablative patterns may be needed to produce a particular **lesion** (e.g., deeper, shallower, symmetric, asymmetric, shaped, etc.). Accordingly, the **antenna** device may be arranged to provide other ablative patterns. For example, the **antenna** device may be arranged to form a cylindrical ablative pattern that is evenly distributed along the length of the **antenna**, an ablative pattern that is directed to one side of the **antenna** device, an ablative pattern that supplies greater or lesser energy at the distal end of the **antenna** device and/or the like. Several embodiments associated with adjusting the ablative pattern of the **antenna** device will now be described in detail.

In one embodiment, the thickness of the **antenna** enclosure is varied along the longitudinal length of the **antenna** device in order to adjust the radiation pattern of the electromagnetic field to produce a better temperature profile during ablation. That is, the **antenna** enclosure thickness can be used to improve field characteristics (e.g., shape) of the electromagnetic...

...an increase in radiation efficiency. Thus, by varying the thickness along the length of the **antenna**, the amount of energy being delivered to the tissue can be altered. As such, the...

...varied to compensate for differences found in the tissue being ablated. In some cases, the **antenna** device can be configured to deliver a greater amount of energy to a specific area and in other cases the **antenna** device can be configured to deliver energy more uniformly along the length of the **antenna**. For instance, if the delivered energy at the proximal end of the **antenna** is greater than the energy at the distal end, then the thickness of the dielectric...

...to reduce the radiation efficiency and therefore create a more uniform radiation pattern along the **antenna**. Consequently, a more uniform heating distribution can be produced in the tissue to ablate.

In an alternate implementation of this embodiment, as shown in Fig. 10, the **antenna** device 30 includes a tuning sleeve 77 for altering the radiation pattern of the **antenna** device 30. The tuning sleeve 77 is formed from a suitable dielectric material and is arranged to increase the thickness of the **antenna** enclosure 37. By way of example, the tuning sleeve may be formed from the same material used to form the **antenna** enclosure. In some embodiments, the tuning sleeve 77 is integrally formed from the **antenna** enclosure 37 and in other

embodiments, the tuning sleeve 77 is coupled to the **antenna** enclosure 37. Furthermore, the tuning sleeve 77 is disposed around the periphery of the **antenna** enclosure 37 and may be positioned anywhere along the length of the **antenna** device 30. By way of example, the tuning sleeve may be positioned at the proximal end or distal end of the **antenna** device, as well as anywhere in between the proximal and distal ends of the **antenna** device. As should be appreciated, the position and length of the tuning sleeve 77 may also be adjusted to alter the radiation pattern of the **antenna** device. Although the tuning sleeve is shown as surrounding the **antenna** enclosure, it should be noted that it may also be circumferentially segmented. In addition, it of sleeves may be used.

In some embodiments, the tip of the **antenna** wire can be exposed to further alter the field characteristics. An exposed tip generally produces...

...firing", which can be used to produce more energy at the distal end of the **antenna**. In other embodiments, the stub tuner may be used to alter the radiation pattern of the **antenna** device. In other embodiments, the director rods may be used to alter the radiation pattern of the **antenna** device.

In another embodiment, as shown in Fig. 11, the **antenna** device 30 includes a reflector 71, which is arranged to direct a majority of an electromagnetic field to one side of the **antenna** wire 36 and thus to one side of the **antenna** device 30. In this embodiment, the reflector 71 is positioned laterally to a first side of the **antenna** wire 36 and is configured to redirect a portion of the electromagnetic field that is transmitted towards the reflector 71 to a second side of the **antenna** wire 36 opposite the reflector 71. Correspondingly, a resultant electromagnetic field including a portion of...

...electromagnetic field is directed in a desired direction away from the second side of the **antenna** wire 36. The desired direction is preferably in a direction towards the tissue to be ablated and thus the reflector is disposed on the side of the **antenna** device opposite the direction set for ablation. Furthermore, the reflector is disposed substantially parallel to the **antenna** to provide better control of the electromagnetic field during ablation.

The reflector is generally coupled to the outer conductor of the transmission **line**. Connecting the reflector to the outer conductor serves to better define the electromagnetic field generated during use. That is, the radiated field is better confined along the **antenna**, to one side, when the reflector is electrically connected to the outer conductor of the transmission **line**. The connection between the reflector and the outer conductor may be made in any suitable...

...In other embodiments, the reflector can be formed from the outer conductor of the transmission **line** itself. This is typically more difficult from a manufacturing standpoint but has the advantage of...

...a more rugged connection between the reflector and the outer conductor. In other embodiments, metallization **techniques** are used to apply a reflective surface onto the **antenna** enclosure.

As can be appreciated, by those familiar with the art, by forming a concentrated...

...generally required from the power source, and less power is generally lost in the transmission **line**. Additionally, this arrangement may be used to form **linear lesions** that are more precise.

Furthermore, the reflector 71 is typically composed of a conductive, metallic...

...arcuate or meniscus shape (e.g., crescent), with an arc angle that opens towards the **antenna** wire 36. Flaring the reflector 71 towards the **antenna** wire 36 serves to better define the electromagnetic field generated during use. The arc angle...

...if the arc angle 90 is greater than 180(degree) the radiation efficiency of the **antenna** arrangement decreases significantly.

Turning now to Figs. 12A & 12B, an alternative embodiment to the present...

...its deployed position (as shown in Fig. 12B). Furthermore, the distal portions of the transmission **line** 28 are appropriately sized such that only the dielectric material medium 33 and the inner conductor 31 are slideably received in the **lumen** 22 of the metallic needle shaft 44. That is, a distal portion of the outer...

...32 has been removed so that the outer conductor 32 is not carried by the **lumen** 22 of the needle shaft 44. As such, the contact member 60 is adapted to...

...shaft 44 can act as an extension of the outer conductor 32 of the transmission **line** 28.

For ease of discussion, portions of the ablation tool 24 that are disposed proximally...

...conductor 31B, the dielectric material 33B and the metallic needle shaft 44 creates a distal **coaxial cable** 28B. That is, the needle shaft 44 conductively functions as a shield for the transmission **line** 28 from the access opening 46 to the distal penetration opening 47 of the probe ...

...in Fig. 12B, this shielding effect commences when the outer conductor 32 of the transmission **line** 28 ...therefore be in conductive communication with the metallic needle shaft 44 at least when the **antenna** device 30 is radiating electromagnetic energy.

As shown in Fig 12B, the contact member 60...

...adapted to electrically contact the proximal part 46 of the needle shaft 44 when the **antenna** device 30 is fully extended through the needle shaft 44 and into the targeted organ...

...As it was explained earlier, it is also important to match the impedance of the **antenna** with the impedance of the transmission **line** . As is well known to those skilled in the art, if the impedance is not matched to the transmission **line** , the microwave power is reflected back to the generator and the overall radiation efficiency tends to be well below the optimal performance. Accordingly, the dimensions of the distal **coaxial cable** elements are generally selected to match the impedance of the proximal transmission **line** . As should be appreciated, the cross sectional dimensions of 28B, 31B and 33B may be different from 28A, 31A and 33A.

With regards to the length of the **antenna** device 30, in the configuration of Figs. 12A&B, the length is generally defined from the center of the distal penetration opening 47 to the distal end of the **antenna** wire 36. Several important factors that will influence the **antenna** length include the desired length of the ablation, the **antenna** configuration, the frequency of the electromagnetic wave and the impedance match of the **antenna** within the tissue or the organ cavity. The matching of the **antenna** is performed by adjusting its length so that the radiation efficiency is adequate when the **antenna** is used in



the tissue or in the organ cavity. As an example, the radiation efficiency is generally adequate when the return loss of the **antenna** is in the range of -10 dB to -13 dB at 2.45 GHz. Instruments...

...be designed by varying the antenna length. For example, in microwave coronary applications for treating **atrial fibrillation**, the **antenna** device may have an **antenna** wire diameter of about 0.013 inch, a dielectric material medium diameter of about 0...

...and a length in the range of approximately 20 mm to 30 mm.

The distal **coaxial cable** can also be used as a serial stub tuner to match the impedance of the **antenna** device 30 and the transmission line 28. This arrangement is advantageous since, while maintaining the electrical continuation and the impedance match between the generator and the **antenna**, the diameters of the inner conductor 31 and the dielectric material medium 33 can be...

...is illustrated wherein the ablation assembly 10 includes a clamping portion 79 for positioning the **antenna** device 30 proximate the wall 82 of the organ 18. The clamping portion 79 and the **antenna** device 30 are arranged to facilitate **linear** positioning of the **antenna** device 30. The clamping portion 79 generally includes a clamping finger 81 and a bar ...

...portion 79 is also arranged to be substantially aligned (in the same plane) with the **antenna** device 30 when the **antenna** device 30 is in its angular position.

Accordingly, when the **antenna** device 30 is properly positioned, the clamping portion 79 is moved in a direction towards the organ 18 to pinch the organ wall between the **antenna** 30 and the clamping finger 81. That is, the clamping finger 81 is moved to...

...wall 88 of the organ 18, wherein after contact and upon further finger movement the **antenna** device 30 is forced to move in a direction towards the probe 12. As a result, the **antenna** device 30 and clamping finger 81 exert opposite forces on opposite sides of the organ wall. By way of example, the finger and the **antenna** device can be used to sandwich the myocardium of the heart wherein the finger is applying a force to the epicardial surface and the **antenna** device is applying an opposing force to the endocardium. This particular approach tends to create a more uniform ablating surface, which as result, produces a better **linear lesion**.

The clamping finger is generally configured to be parallel to the angular position of the deployed **antenna** device. By way of example, if the **antenna** device is configured to have an angle of about 60 degrees relative to the axis...

...of about 60 degrees relative to the axis of the probe. In this manner, the **antenna** device and clamping finger can pinch the organ wall evenly. Alternatively, the clamping finger can...

...clamping finger generally has a length that is substantially equivalent to the length of the **antenna** device. However, it should be noted that the length may vary according to the specific for physically actuating the **linear** movement, a knob or jack for mechanically actuating the **linear** movement, or an air supply for powering the **linear** movement. A locking mechanism may also be used to lock the engagement between the clamp finger and the **antenna** device so that the **antenna** device does not move from the target area during ablation.

Moreover, a seal may be...

...be used to pinch the organ wall between the inflated balloon and the angularly positioned **antenna** device.

Turning now to Figs. 14A & 14B, an alternative embodiment to the present invention is...

...plane 89 generally provides a metallic surface that attracts the electric field generated by the **antenna** device 30 and therefore a more intense electromagnetic field 90 is produced between the **antenna** device 30 and the ground plane 89. Accordingly, the electromagnetic field 90 emitted by the **antenna** device 30 is more constrained in the tissue 35 between the **antenna** device 30 and the ground plane 89, which as a result helps to create the...

...with the art, inserting the tissue to ablate between the ground plane 89 and the **antenna** 30 has several potential advantages over conventional **antenna** structures. For example, by forming a concentrated electromagnetic field, deeper penetration of biological tissues may...

...generally required from the power source, and less power is generally lost in the transmission **line**, which tend to decrease its temperature. Additionally, this arrangement may be used to form **lesions** that are more precise.

In this embodiment, the ground plane 89 is electrically coupled to the outer conductor 32 of the transmission **line** 28. The ground plane 89 is generally disposed on the needle shaft 44 of the probe 12 at a predetermined distance Q away from the deployed **antenna** device 30 (as shown in Fig. 14B). The predetermined distance Q is arranged to place the ground plane 89 in close proximity to the **antenna** device 30, and outside the outer wall of the organ 18 when the needle shaft...

...ground plane 89 is generally configured to be parallel to the angular position of the **antenna** device 30. By way of example, if the **antenna** device 30 is configured to have an angle of about 60 degrees relative to the...

...to have an angle of about 60 degrees relative to the axis of the transmission **line**. In this manner, the **antenna** and the ground plane can couple energy more evenly. Alternatively, the ground plane can be...

...ground plane generally has a length that is substantially equivalent to the length of the **antenna** device 30. By way of example, a ground plane length between about 20 mm and...

...arranged to be substantially aligned (in the same plane) with the angular component of the **antenna** device 30.

The ground plane 89 may be formed from a wire, strip or rod...

...described above in Fig. 13, can be arranged to be a ground plane for the **antenna**. In other embodiments, the ground plane may be flexible in order to follow the natural...

...organ.

In an alternate embodiment, the ground plane may be properly positioned across from the **antenna** device with a ground plane positioner. The ground plane positioner generally includes tubular member having predetermined position that is substantially aligned with the deployed **antenna** device such that the organ wall is disposed between the ground plane and the **antenna** device. In one embodiment, the assembly may include a biasing member that is specifically formed...

...plane to a predetermined bent position. In another embodiment, the assembly may include a steering **system** for bending the ground plane to a predetermined bent position. In another embodiment, the needle...

...the ground plane 96 is electrically coupled to the outer conductor 32 of the transmission **line** 28. In this particular embodiment, the tubular member includes a curved section 95 which redirects...

...opening 97 and to an outer wall position that is substantially aligned with the angled **antenna** device 30. Additionally, the ground plane 96 may be fixed to the transmission **line** 28 such that when the **antenna** device 30 is deployed so is the ground plane 96.

Turning now to Fig. 16...

...used for ablating cardiac tissues, in accordance with one embodiment of the present invention. The **ablation** assembly 10 is especially beneficial in navigating around certain regions of the heart 200. For example, the **ablation** assembly 10 may be used to bypass the layers of fat 202 or veins 204 that surround the **epicardial** surface 206 (e.g., outer wall) of the heart 200. By way of example, the...

...be the coronary sinus, which is located just superior to the junction between the left **atrium** 240 and the left ventricle 246. As mentioned, fat 202 is a good **microwave** absorber and a very poor thermal conductor. Furthermore, veins 204 readily transfer heat through blood...

...are very difficult to ablate through from the epicardial surface (not enough thermal energy to **ablate** ). Accordingly, by positioning the

**antenna** device 30 inside a cavity 208 of the heart 200 (e.g., through the layer...

...be supplied to the endocardium 210 rather than the obstructed epicardial surface 206 thereby effectively **ablating** the targeted tissue. By way of example, the cavity 208 may be the left **atrium** 240, the right atrium 242, the left ventricle 246 or the right ventricle 244.

The...

...cardiac tissues using the ablation assembly 10 will now be described.

In one implementation, the **ablation** assembly 10 is used to create **lesions** between any of the pulmonary veins 212 of the heart 200 in order to treat **atrial** fibrillation. In another implementation, the ablation assembly 10 is used to create lesions from one of the pulmonary veins 212 to the mitral **valve** 213 of the heart 200 in order to avoid macro-reentry circuit around the pulmonary veins in a **lesion** pattern used to treat atrial fibrillation. In another implementation, the ablation assembly 10 is used to create lesions from one of the pulmonary veins 212 to the left **atrial** appendage of the heart 200 also to avoid macro-reentry circuit around the pulmonary veins in a **lesion** pattern used to treat **atrial** fibrillation.

In one implementation, the **ablation** assembly 10 is used to create **lesions** between the inferior caval vein 216 to the tricuspid valve 214 of the heart 200...

...the right atrium 242 of the heart 200 in order to treat typical or atypical **atrial** flutter. In another implementation, the **ablation** assembly 10 is used to create **lesions** from the cristae terminalis to the fossae ovalis in the right **atrium** 242 of the heart 200 in order to treat typical or atypical atrial flutter. In...

...ablation assembly 10 is used to create lesions on the lateral wall of the right **atrium** 242 from the superior 220 to the inferior vena cava

216 in order to treat atypical atrial **flutter** and/or atrial **fibrillation** .

Although a wide variety of cardiac **procedures** have been described, it should be understood that these particular **procedures** are not a limitation and that the present invention may be applied in other areas of the heart as well.

A **method** for using the described microwave ablation assembly in treating the heart will now be described as well as organ ducts, may be treated with ablation assembly. The **method** includes providing an ablation assembly such as any one of the ablation assemblies described herein. More particularly, the **method** includes providing a surgical device 10 having a probe 12 and an elongated microwave ablation...

...The distal end 16 is adapted to penetrate through a muscular wall 222 (e.g., **myocardium** ) of the heart 200. Furthermore, the elongated microwave **ablation** arrangement 24 includes a distal **antenna** 30 coupled to a transmission **line** , which in turn is coupled to a microwave energy source at a proximal end thereof. In accordance with the present invention, the **method** includes introducing the surgical device 10 into a body cavity 230. This may be by...

...posterior thoracotomy, a lateral thoracotomy (as shown in Fig. 10), or a sternotomy. The surgical **procedure** can also use an endoscope in order to visualize the ablation device during the placement. These **procedures** are generally well known to those skilled in the art and for the sake of brevity will not be discussed in detail.

The **method** further includes penetrating the muscular wall 222 of the heart 200 with the distal end...

...art and for the sake of brevity will not be discussed in more detail.

The **method** also includes introducing the elongated microwave ablation device 24 into the passage of the elongated probe 12 and advancing the **antenna** 30 past the distal end 16 of the probe 12 such that the **antenna** 30 is disposed inside the interior chamber 208 of the heart 200. Upon advancement, the **antenna** 30 preferably assumes a predetermined position that substantially matches the shape and/or angular position of the wall to be ablated. By way of example, the position may place the **antenna** substantially parallel to the interior surface 210 (e.g. endocardium) of the penetrated muscular wall...

...for example, with a biasing member, a steering wire or a curved probe. Furthermore, the **method** includes generating a microwave field at the **antenna** that is sufficiently strong to cause tissue ablation within the generated microwave field.

In accordance...

...another aspect of the present invention, the ablation assembly includes a needle and a transmission **line** having a longitudinal axis. The needle is adapted to be inserted into a body cavity...

...needle is also configured for insertion into a cavity within the organ and includes an **antenna** for transmitting electromagnetic energy. The transmission **line** is coupled to the **antenna** and configured for delivering electromagnetic energy to the **antenna** . Furthermore, the ablation assembly is arranged so that when the needle is finally inserted into the organ cavity, the **antenna** lies at an angle relative to the longitudinal axis of the transmission **line** . In most cases, the needle or the transmission **line** is pre-shaped or bent at a predetermined position that is arranged to substantially match...

...position of the wall to be ablated. In other cases, a biasing member or steering **system**, in a manner similar to biasing member and steering **system** described above, may be used to provide angled positioning.

Turning now to Figs 18-21...

...avoid damaging the organ 106 during positioning. The ablation assembly 100 further includes a transmission **line** 108 having a longitudinal axis 110 and a distal end 112 that is coupled to...

...field sufficiently strong to cause tissue ablation. At the proximal end 118 of the transmission **line** 110 is an electrical connector 120 adapted to electrically couple the **antenna** to an electromagnetic energy source (not shown). As shown, the needle 102 is bent at an angle 116 relative to the longitudinal axis 110 of the transmission **line** 108. In most embodiments, the bend is arranged to easily position the **antenna** parallel to the tissue to ablate by taking into consideration the angle of approach (the the **epicardial** surface (e.g., outer wall) of the heart. Furthermore, the angled position of the needle assures that the **ablative** energy will be accurately transmitted in the targeted ablation region.

Referring to Fig. 21, the needle 102 includes an elongated **antenna** 130 and an **antenna** enclosure 132 that are adapted to pierce through organ 106 at a distal penetration end...

...needle or a beveled point chamfered needle which forms sharp cutting edge. As shown, the **antenna** 130 is encapsulated by the **antenna** enclosure 132, which is generally better suited to remove the high electromagnetic field concentration that is normally obtained when the metallic part of the **antenna** is in direct contact with the tissue. A high field concentration can create a high surface temperature on the tissue to **ablate** which is not desirable, especially for **cardiac** applications. The **antenna** enclosure 132 may be made of any suitable dielectric material (e.g., low loss tangent...

...described in great detail above, it may be desirable to adjust the thickness of the **antenna** enclosure in order to provide better impedance matching between the **antenna** and the tissue targeted for ablation. It is contemplated, however, that needle **antenna** enclosures having a thickness between about 0.002 inches and about 0.015 inches, and more particularly about 0.005 inches work well.

It should also be noted that the **antenna** enclosure may not be required for all ablation assemblies. By way of example, Figs. 22 & 24 show the ablation assembly 100 with an exposed **antenna** 130 having no **antenna** enclosure. However, it should be noted that in most situations the **antenna** enclosure is configured to insulate the **antenna** to avoid the charring and tissue destruction effects that are commonly experienced when the ablative elements, and more particularly, the metallic parts of the **antenna**, are directly in contact with the body's tissue or fluid.

The **antenna** 130 is formed from a conductive material. By way of example, spring steel, beryllium copper, or silver plated copper work well. Further, the diameter of the **antenna** 130 may vary to some extent based on the particular application of the ablation assembly...

...the type of material chosen. By way of example, in systems using a monopole type **antenna**, wire diameters between about 0.005 inch to about 0.020 inches work well. In the illustrated embodiment, the diameter of the **antenna** is about 0.013 inches.

As mentioned, the field generated by the **antenna** will be roughly consistent with the length of the **antenna**. That is, the length of the electromagnetic field is generally constrained to the longitudinal length

of the **antenna** . Therefore, the length of the field may be adjusted by adjusting the length of the **antenna** . Accordingly, ablation arrangements having specified ablation characteristics can be fabricated by building ablation arrangements with different length **antennas** . By way of example, **antennas** having a length between about 20 mm and about 50 mm, and more particularly about 30 mm work well. Furthermore, the **antenna** shown is a simple longitudinally extending exposed wire that extends distally from the inner conductor. However it should be appreciated that a wide variety of other **antenna** geometries may be used as well. By way of example, helical coils, flat printed circuit **antennas** and other **antenna** geometries will also work well. Additionally, it should be understood that longitudinally extending **antennas** are not a requirement and that other shapes and configurations may be used. For example, the **antenna** may be configured to conform to the shape of the tissue to be ablated or to a shape of a predetermined ablative pattern for creating shaped **lesions** .

Referring back to Fig. 21, the transmission **line** 108 generally includes an inner conductor 134 and an outer conductor 136 separated by a ...

...the outer conductor 136 is exposed, the generated electromagnetic field is more constrained to the **antenna** and therefore the radiation efficiency tends to be greater. By way of example, an exposed...

...ablation arrangement can be made with or without an exposed outer conductor.

Furthermore, the transmission **line** 108 is provided by a conventional fifty (50) ohm coaxial design suitable for the transmission...

...Germany have been used with success.

In most embodiments, the proximal end 114 of the **antenna** 130 is coupled directly or indirectly to the distal end 112 of the inner conductor 134 of the transmission **line** 108. A direct connection between the **antenna** 130 and the inner conductor 134 may be made in any suitable manner such as...

...As was described in great detail above, it may be desirable to indirectly couple the **antenna** to the inner conductor through a passive component in order to provide better impedance matching between the **antenna** device and the transmission **line** . In other embodiments, the **antenna** 130 can be integrally formed from the transmission **line** 108 itself. This is typically more difficult from a manufacturing standpoint but has the advantage of forming a more rugged connection between the **antenna** and the transmission **line** .

The ablation assembly 100 is preferably thin having a diameter in the range of between...

...flexible to accommodate normal operational use, yet be sufficiently rigid to prevent buckling of the **line** during penetrative manipulation of the needle into the targeted organ.

In one embodiment, the ablation...

...the needle 102 at an angle relative to the longitudinal axis 108 of the transmission **line** 110. As shown in Fig. 21, the bend 150 is placed along a distal portion of the transmission **line** . Alternatively, the bend 150 may be placed along a proximal portion of the needle as...

...ablated. Furthermore, bend 150 is arranged to be sufficiently rigid to prevent buckling of the **line** during penetrative manipulation of the needle into the targeted organ.

In Fig. 19, the ablation...

...may be configured to provide a range of angled bends. By way of example, an **antenna** position having an angle in the range of between about 45 degrees to about 135 degrees with respect to the longitudinal axis of the transmission **line** works well. However, it should be noted that this is not a limitation and that...

...used. By way of example, the ablation assembly can be configured to have multiple bends, **curvilinear** bends, rectilinear bends, three dimensional bends or have a shape that conforms to the shape of the tissue to be ablated or the ablating **line** desired.

For ease of discussion, Figs. 25A & 25B show a variety of ablation assembly configurations...

...to longitudinal axis 110. Again, these angular positions are important parameters for ensuring that the **antenna** device is properly positioned in a direction towards the tissue targeted for ablation.

Turning now...

...102 proximate the tissue targeted for ablation. The handle 160 is disposed on the transmission **line** 108 at a predetermined distance X away from the bent portion 150 of the assembly...

...handle is arranged to provide additional support (rigidity and strength) at the junction between the **antenna** and the inner conductor of the transmission **line**. In another implementation, the handle is arranged to enclose an impedance matching device located between the **antenna** and the inner conductor. Furthermore, in a manner analogous to the clamping portion (Fig. 13) described above, the handle can be arranged to be slidably coupled to the transmission **line** such that the handle can be used to clamp the wall of the organ between...

...the handle may include a balloon for biasing contact between the handle and the bent **antenna**.

Turning now to Figs. 27A-27C, an alternative embodiment to the present invention is illustrated...plane 170 generally provides a metallic surface that attracts the electric field generated by the **antenna** 130 and therefore a more intense electromagnetic field 180 is produced between the **antenna** 130 and the ground plane 170. As a result, a more efficient, controlled and concentrated...

...the ground plane 170 is electrically coupled to the outer conductor 136 of the transmission **line** 108. The ground plane 170 is generally disposed on the transmission **line** 108 at a predetermined distance Y away from the **antenna** 130 of the needle 102. The predetermined distance Y is arranged to place the ground...

...to have an angle of about 60 degrees relative to the axis of the transmission **line**, then the ground plane may be configured to have an angle of about 60 degrees relative to the axis of the transmission **line**. In this manner, the **antenna** and the ground plane can couple energy more evenly. Alternatively, the ground plane can be...

...ground plane generally has a length that is substantially equivalent to the length of the **antenna** 130. By way of example, a ground plane length between about 20 mm and about...

...be part of the handle. In another implementation, the electrode is movably coupled to transmission **line**. For example, the ground plane may be pivotly or slidably coupled to the transmission **line**. In another

implementation, the ground plane is biased to contact the tissue.

A **method** for using the described needle ablation assembly in treating an organ will now be described. The **method** includes providing a surgical device 100 having a needle 102 coupled to a transmission **line** 108. The transmission **line** 108 is arranged to have a portion with a longitudinal axis 110 and a proximal...

...104 that is adapted to penetrate through a wall of an organ 106 and an **antenna** 130 for generating a **microwave** field. By way of example, the organ may be a human heart and the wall may be the **myocardium** of the heart. The **antenna** 130 is also arranged to be in an angular position relative to the longitudinal axis 110 of the transmission **line** 108. By way of example, the needle or the transmission **line** may be pre-shaped or bent at a predetermined angular position.

In accordance with the present invention, the **method** includes introducing the surgical device 100 into a body cavity. This may be by penetration...

...be provided through the thorax region of the body or through an opened chest. The **method** further includes penetrating a wall of the organ 106 with the distal end 104 of...art and for the sake of brevity will not be discussed in more detail.

The **method** also includes positioning the needle 102 inside the interior chamber of the organ 106 such that the **antenna** 130 substantially matches the shape and/or angular position of the wall to be ablated. By way of example, the position may place the **antenna** substantially parallel to the interior surface of the penetrated wall and proximate the targeted tissue. Furthermore, the **method** includes generating a microwave field at the **antenna** that is sufficiently strong to cause tissue ablation within the generated microwave field.

Although only...

...or scope of the invention. Particularly, the invention has been described in terms of a **microwave** ablation assembly for **cardiac** applications. However, it should be appreciated that the present invention could be used for a...

...applications as well. By way of example, the present invention may be used in most **procedures** relating to the ablation of internal biological tissues, and more particularly, to the ablation of...

...transducer, while the transmission element may be a metallic wire, a fiber optic or a **tube** carrying cooling fluid.

Furthermore, while the invention has been described in terms of several preferred...

...and equivalents, which fall within the scope of this invention. By way of example, the **ablation** assembly may also include a series of mapping electrodes to detect electrophysiological signals from the...

...be used to map the relevant region of the heart prior to or after an **ablation procedure**. The electrodes may also be used to monitor the patient's condition and/or the nature of the ablation **process**. The electrodes may be disposed along the **antenna** device in the **antenna** region, along the transmission **line**, or along the clamping finger. The electrode bands may optionally be divided into a plurality....

...cables or any other suitable thermometry devices. The thermometry elements may be disposed along the **antenna** device, along the transmission **line**, or along the clamping finger.



Moreover, although the ground plane has been shown and described as being directly connected to the outer conductor of the transmission line, it may be indirectly grounded through an external conductor. This type of arrangement also creates...

...organ to seal the puncture site. Additionally, the ablation assembly may include a chemical delivery **system** for injecting chemical agents into the penetrated tissue. Further still, purse string sutures may be...

...the organ. It should also be noted that there are many ways of implementing the **methods** and apparatuses of the present invention. It is therefore intended that the following appended claims...

...CLAIMS to extend at an angle relative to a longitudinal axis of the introducer.

55. The **system** of claim 54 wherein said distal end of the introducer extends at an angle of...

...about 0 and 90 degrees relative to the longitudinal axis of the introducer.

56. The **system** of claim 54 wherein said distal end of the introducer extends at an angle of...

...duct.

58. The device of claim 57 wherein said energy delivery portion comprises a microwave **antenna** which is located within said distal end portion of the shaft.

59. The device of claim 57 wherein said energy delivery portion includes a needle microwave **antenna**.

60. The device of claim 59 wherein an outer diameter of the needle **antenna** is less than about 3 mm.

61. The device of claim 57 wherein said distal...The device of claim 76 wherein said microwave energy delivery means comprises a needle microwave **antenna**.

78. An ablation device comprising an elongated shaft having a proximal end portion, a distal...

...end portion, a distal end portion having a sharpened distal end, and at least one **lumen** which is sized and dimensioned for slidable receipt of the ablation device therethrough.

86. The device of claim 78 wherein the energy delivery portion comprises a microwave **antenna**.

87. The device of claim 78 wherein the energy delivery portion has a sharpened distal...

...portion of a lateral wall of the right atrium to treat typical or atypical atrial **flutter**.

91. The device of claim 78 wherein the energy delivery portion is configured to be...

22/3,K/12 (Item 12 from file: 348)  
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Catheter **assembly and associated treatment** catheter  
**Katheteranordnung und Behandlungskatheter** dafur  
**Ensemble** catheter **et** catheter **de traitement associe**  
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Catheter **assembly and associated treatment** catheter  
**Ensemble** catheter **et** catheter **de traitement associe**  
...INTERNATIONAL PATENT CLASS: **A61B-005/042**

...ABSTRACT A1

The invention relates to a **catheter** assembly comprising a guiding **catheter** with a pliable **tube** -like basic body with a distal and a proximal end and a registration **catheter** slidable through a **lumen** of the guiding **catheter** which also has a **tube** -like basic body with a distal and a proximal end. In released state, the guiding **catheter** is bent at its distal end. The treatment **catheter** comprises at its distal end an end-section substantially shaped like part of a circle...

...of electrodes which are connected to conductors extending through the basic body of the treatment **catheter** to its proximal end. (see image in original document) ...

...SPECIFICATION A1

The invention relates to a **catheter** assembly to be used for cardiological purposes. It relates in particular to a **catheter** assembly for the registration of electrical impulses in the area surrounding the tricuspid valve in the right atrium of the heart of a patient.

When treating certain types of **tachycardia** it is advisable to measure the electrical activity inside the heart, and to ablate the...

...in question, when for instance an abnormality has been detected.

The invention relates to a **catheter** assembly with which a

*good !!!*  
*see claims*  
*potential*  
*35 usc 102 !!*

significant area surrounding the tricuspid valve on the atrial side can ...

...both the measurement of electrical activity and for instance the ablation of tissue.

With the **catheter** assembly of the invention as characterised in claim 1, the end-section of the treatment **catheter** which is substantially shaped like part of a circle, can be positioned, around the tricuspid...

...wall of the atrium and be used to carry out the required treatment.

The guiding **catheter** is first inserted into the body of the patient by means of a **guide wire**, whereby the **curve** at the distal end of the guiding **catheter** is advanced to a position above the tricuspid valve via the inferior vena cava. The end of the guiding **catheter** is directed towards the valve. Subsequently the treatment **catheter** is introduced via the guiding **catheter**. As soon as the end-section of the treatment **catheter** passes the end of the guiding **catheter**, it assumes its original shape and can be placed against the wall of the **atrium** surrounding the valve. In that position, the electrical activity can be registered or tissue **ablated** by means of the electrodes.

According to a further development the treatment **catheter** can be manufactured in such a way, that the centre of the end-section shaped...

...a circle is substantially placed on the continuation of the basic body. When the treatment **catheter** is turned inside the guiding **catheter** on its longitudinal axis, the end-section shaped like part of a circle will trace...

...the entire circumference of the cardiac valve can be covered.

The embodiment of the treatment **catheter** as claimed in claim 7 is preferably employed for treatment of the area on the...

...description with reference to the attached figures.

Fig. 1 represents a perspective view of a **catheter** assembly according to a first embodiment of the invention.

Fig. 2 shows a treatment **catheter** for a **catheter** assembly according to another embodiment.

Fig. 3 shows a cross-section of a heart with the **catheter** assembly of fig. 1 during treatment.

Fig. 4 represents the heart of fig. 3 in...

...in fig. 3.

Fig. 5 shows a view corresponding to fig. 4 with the treatment **catheter** as shown in fig. 2.

The **catheter** assembly 1 as shown in fig. 1 comprises a guiding **catheter** 2 and a treatment **catheter** 3.

In the usual manner, the guiding **catheter** 1 has a **tube**-like basic body with a proximal end and a distal end 5. At the proximal end a connecting member has been arranged.

At the distal end 5 the guiding **catheter** has a **curve** 6 which defines an angle of the order of 120 degrees.

On insertion, the guiding **catheter** 2 will be straightened at the **curve** 6 by means of a **guide wire**. Once the distal end 5 has arrived in the right atrium of the heart of a patient, the **guide wire** is removed and the distal end 5 will assume its original, bent shape.

The treatment **catheter** 3 has at its distal end 8 an end-section 9 which is substantially shaped...

...way that the end-section 9 is placed, in the released state of the treatment **catheter** 3, in a plane at right angles to the longitudinal axis of the basic body. As the **catheter** 3 has been made of a pliable

material, the curved end can be straightened completely and introduced in this unbent form via the lumen 12 of the guiding catheter 2 into a patient.

In the preferred embodiment 4 shown, the end-section 9 shaped...

...11. These electrodes are connected to conductors 13 extending through the basic body of the catheter to its proximal end 7. These conductors 13 are connected to a connector 14 which in its turn is connected to a control means not specified here.

The treatment catheter 3 of fig. 1 comprises an end-section 9 which extends, as seen from the side of the interatrial septum.

The treatment catheter 15 of fig. 2 corresponds substantially to the treatment catheter 3 of fig. 1, whereby however the end-section 16 shaped like part of a...

...section 16 carries a number of electrodes 17 which, at the proximal end of the catheter, can be connected to a control device also by means of conductors.

Fig. 3 shows a catheter assembly according to the invention in the position of use.

Fig. 3 represents a cross...

...and a right ventricle 22, with in between the tricuspid valve 23.

When using the catheter assembly according to the invention, the guiding catheter 2 is first introduced into the patient as described above in such a way, that its distal end is positioned inside the right atrium 21. On removal of the guide wire the curved end-section 6 of the guiding catheter will be released, so that the end of the guiding catheter 2 will be turned towards the centre of the valve 23.

Next the treatment catheter 3 is introduced via the lumen 12 of the guiding catheter 2. When the curved end-section has passed through the tip of the guiding catheter 2, it assumes the pre-bent shape, whereby the end-section 9 is placed in...

...activity can be measured and the tissue, if necessary, ablated.

The physician carrying out the procedure can optimize the contact between the end-section 9 shaped like part of a circle and the wall by rotating the proximal end of the catheter 3 a little. The circular end-section will also rotate in that case, whereby the basic body of the treatment catheter will function as a flexible axis.

As has been mentioned before, the end-section 9...

...scanned.

As can be seen in fig. 4 and 5 the two differently shaped treatment catheters 3 and 15 respectively are used for treatment of the atrial wall surrounding the tricuspid...

...of the right atrial free wall respectively. The shape of each of the two treatment catheters 3 and 15 has been adjusted in detail to the wall with which it has...

...CLAIMS A1

1. Catheter assembly comprising a guiding catheter with a pliable tube-like basic body with a distal and a proximal end and a registration catheter slidable through a lumen of the guiding catheter which also has a tube-like basic body with a distal and a proximal end, wherein the guiding catheter is, in released state, curved at its distal end; and the treatment catheter comprises at its distal end an end-section substantially shaped like part of a circle...

- ...of electrodes which are connected to conductors extending through the basic body of the treatment **catheter** to its proximal end.
2. **Catheter** assembly as claimed in claim 1, wherein the curve of the guiding **catheter** defines an angle between 90 and 150 degrees.
  3. **Catheter** assembly as claimed in claim 2, wherein the curve of the guiding **catheter** defines an angle of at least 120 degrees.
  4. Treatment **catheter** for a **catheter** assembly as claimed in one of the previous claims, comprising a **tube** -like basic body with a distal and a proximal end, wherein the treatment **catheter** comprises at its distal end an end-section substantially shaped like part of a circle...
- ...a number of electrodes connected to conductors extending through the basic body of the treatment **catheter** to its proximal end.
5. Treatment **catheter** as claimed in claim 4, wherein the centre of the end-section shaped like part of a circle is situated on the continuation of the basic body.
  6. Treatment **catheter** as claimed in claim 4 or 5, wherein the end-section shaped like part of a circle extends over an arc of substantially 180 degrees.
  7. Treatment **catheter** as claimed in claim 6, wherein the end-section shaped like part of a circle extends, as seen from the basic body; to the left.
  8. Treatment **catheter** as claimed in claim 6, wherein the end-section shaped like part of a circle...

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**CARDIAC ABLATION DEVICES**

**DISPOSITIFS D'ABLATION CARDIAQUE**

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Detailed Description

Claims

Detailed Description

... can be

threaded into the pulmonary vein. The balloon is then advanced  
along the guide **wire** until the tip lodges in the ostium in the  
pulmonary vein. Where the particular pulmonary...

...structures are

forcibly engaged with the tissues. It would be desirable to  
provide an improved **system** and **method** which does not rely on  
such forcible engagement to orient the balloon or other  
ablation...

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...within the heart chamber. For example, the treatment plan may require formation of loop-like **lesions** around the individual ostium of each of several pulmonary veins. It would be desirable to provide apparatus and **methods** which facilitate such repositioning.

Further, it has been proposed that more effective treatment can be provided by ablated generally **linear lesions** along the heart wall in conjunction with - loop-like **lesions**.

However, heretofore it has been proposed to form the **linear lesions** using specialized devices as, for example, **catheters** equipped with a point energy source such as a single pair of electrodes for applying RF energy, so that the **linear lesion** can be traced by moving the **catheter** so as to move the single point source along the heart wall or, alternatively, by **catheters** equipped with numerous energy emitters such as numerous RF electrodes disposed along the length of the **catheter**. Such a **catheter** may be provided as a separate device which must be separately introduced into the heart, thus complicating and prolonging the **procedure**. Alternatively, it has been proposed to provide such a **catheter** as a portion of a **catheter** carrying a device for forming a loop-like **lesion**.

Although this approach theoretically simplifies the task of positioning the needed devices within the heart...

...is in an expanded condition. It would also be desirable to provide a back-up **system** which would minimize the consequences in the unlikely event of a structural failure in one...

...present invention address these needs.

One aspect of the present invention provides apparatus for performing **cardiac ablation** in a mammalian subject. Apparatus according to this aspect of the invention includes an insertable structure which incorporates a **catheter** having proximal and distal ends, as well as an ablation device mounted to the **catheter** adjacent the distal end thereof. The ablation device is adapted for placement within a chamber of the heart of the subject and is adapted to **ablate** a region of the cardiac structure bounding the chamber when the **ablation** device is in an operative configuration. The insertable structure also defines an outlet port open...

...end, and further defines a continuous passageway extending from adjacent the proximal end of the **catheter**. Most preferably, the apparatus according to this aspect of the invention further includes a source...

...a contrast medium adapted for connection to the passageway adjacent the proximal end of the **catheter**. The source of contrast medium is operative to pass contrast medium through the passageway and...

...is in the operative condition when the expansible structure is in its expanded state.

A **method** according to a related aspect of the invention

includes the step of providing an ablation...

...operative configuration with a distal side of the device facing toward a region of the **cardiac** structure to be ablated, and, while the **ablation** device is in its operative configuration, injecting a contrast medium into the chamber on the distal side of the ablation device. The **method** most desirably further includes obtaining one or more images depicting the contrast medium in at...

...a portion of the cardiac structure as, for example, by x-ray or fluoroscopic imaging. **Methods** according to this aspect of the invention allow the physician to confirm placement of the...

...while a balloon or other expansible structure is in its expanded state. Most preferably, the **methods** according to this aspect of the invention are performed without introducing a separate **catheter** to carry the contrast medium, as by using the continuous passageway discussed above in connection with the apparatus. The **methods** according to this aspect of the invention may further include the step of adjusting the position of the **ablation** device, based in part or entirely on the relationship between the ablation device and the **cardiac** structure observed in the imaging step. These **methods** allow the physician to position the device during the **procedure**, without relying on a predetermined mechanical relationship between the device and the cardiac structure.

Apparatus according to a further embodiment of the invention includes a **catheter** and an ultrasonic device having a forward-to-rearward axis. The ultrasonic device is arranged...

...like region surrounding the forward-to-rearward axis. The ablation device is mounted to the **catheter**. Apparatus according to this aspect of the invention includes a steering **system** adapted to selectively vary the disposition of the ablation device and, in particular, the disposition...

...as a balloon structure having a collapsed, inoperative state and an expanded state. The steering **system** preferably is operative to selectively vary the disposition of the ablation device 35 while the...

...balloon-based expanded structure is in an inflated condition. Most preferably, the steering **system** is arranged to selectively vary the disposition of the ultrasonic **ablation** device independently of engagement between the cardiac structure and any element of the apparatus distal to the ultrasonic **ablation** device. Most preferably, the **catheter** has a bendable section located proximally or rearwardly of the forward end of the ablation device, and the steering **system** is arranged to selectively bend this bendable section of the **catheter** under the control of the physician. In a particularly preferred arrangement, the expansible structure includes...

...condition, but facilitates threading of the device through the



body to the heart.

The steering **system** most desirably includes at least one pull wire mechanically connected to the reinforcing structure, typically...

...by pulling on the internal reinforcing structure within the expansible structure tends to bend the **catheter** in such a way that the expansible structure turns about a pivot axis relatively close...

...it easier to maneuver the expanded structure within the confines of a heart chamber.

A **method** of **cardiac ablation** according to a related aspect of the present invention includes the steps of advancing apparatus including a **catheter** bearing an ultrasonic ablation device into the subject until the ultrasonic ablation device is within...

...disposition of the forward-to-rearward axis of the ultrasonic ablation device relative to the **catheter**, and then while the ultrasonic ablation device is in this first disposition, ablating the heart wall to form a first **lesion** by actuating the ablation device to direct ultrasonic waves into at least a portion of a ring-like region surrounding the forward-to-rearward axis of the device. The **method** also includes the step of removing the ultrasonic ablation device from the subject. Most preferably, the **method** further includes the step of repositioning the ultrasonic ablation device from the first disposition to...

...by further selectively varying the disposition of the forward-to-rearward axis relative to the **catheter**, and, while the device is in the second disposition, ablating the heart wall to form a second **lesion**, again by actuating the ablation device to direct ultrasonic waves into the ring-like region...

...Additional repositioning and actuating steps may be employed as well, so as to form further **lesions**. Desirably, at least one of the dispositions of the ablation device is a so-called...

...in close proximity to the wall of the heart. Ablation in this disposition forms a **lesion** in the form of at least a substantial portion of a loop. Alternatively or additionally...

...in close proximity to the wall of the heart.

Ablation in this disposition forms a **lesion** in the form of only a small portion of a loop, approximating a **linear lesion**.

Thus the same tool can be used to form both loop-like **lesions** and substantially **linear lesions**. Most desirably, the ablation device is arranged to focus the ultrasonic waves into the ring...

...or almost all of this energy performs the desirable function of ablating the loop-like **lesion**. However, in the canted

disposition, only a portion of the ablation region is disposed where...

...The emitter assembly includes a tubular piezoelectric element having proximal and distal ends and a **tube**, referred to herein as the "inside **tube**," extending within the tubular piezoelectric element, so that the inside **tube** and the piezoelectric element cooperatively define an annular passageway extending between the proximal and distal...

...adjacent the distal end of the emitter assembly. The apparatus most preferably further includes a **catheter** having proximal and distal ends. The **catheter** has a first **lumen**, referred to herein as a principal **lumen**, most typically disposed adjacent the center of the **catheter**, and also has first and second additional **lumens**. The principal **lumen** communicates with the bore of the inside **tube**. The first additional **lumen** communicates with the proximal end of the annular passageway, and the second additional **lumen** communicates with the interior of the balloon adjacent the proximal end of the emitter assembly...

...include a proximal mounting structure disposed at least partially between the distal end of the **catheter** and the proximal end of the tubular piezoelectric element. The proximal mounting structure desirably defines a first channel which connects the first additional **lumen** of the **catheter** with the annular passageway, a second channel communicating with the second additional **lumen** of the **catheter** and a port communicating with the second channel and with the interior of the balloon, so that the second additional **lumen** communicates with the interior of the balloon through the port.

In the preferred apparatus according...

...the invention, the piezoelectric element can be cooled by directing liquid through the first additional **lumen** of the **catheter** and through the annular channel inside the piezoelectric element.

The liquid passes from the annular...

...through the interior of the balloon back through the port and into the second additional **lumen** of the **catheter**. The principal **lumen** of the **catheter** and the bore of the inside **tube** desirably define a portion of the continuous passageway discussed above. Because the principal **lumen** is not employed in circulation of the cooling liquid, it remains free for purposes such...

...with the distal mounting structure.

Still other aspects of the invention provide alternative structures and **methods**.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic view depicting a **catheter** and ablation device in accordance with one embodiment of the invention, in conjunction with certain...

...of the invention.

FIG. 3 is a diagrammatic sectional view depicting a portion of a **catheter** according to one embodiment of the invention.

FIG. 4 is a sectional view taken along **line 3-3** in FIG. 3.  
FIG. 5 is a fragmentary, diagrammatic elevational view depicting a...

...of the structure depicted in FIG. 14.

FIG. 20 is a sectional view taking along **line 20-20** in FIG. 14.

FIG. 21 is a fragmentary perspective view depicting a portion...

...the structures of FIGS. 14-23 and a portion of the heart wall during a **method** in accordance with one embodiment of the invention.

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FIGS. 25 and 26 are views...

...according to one embodiment of the invention includes an insertable structure 10 incorporating an elongated **catheter** 12 having a proximal end 14, which remains outside of the body, and a distal...  
...distal end. The insertable structure 10 also includes an ablation unit 18 mounted to the **catheter** adjacent distal end 16. Ablation unit 18 incorporates a reflector balloon 20 and a structural balloon 22 having a common wall 24.

Reflector balloon 20 is linked to an inflation **lumen** (not shown) in **catheter** 10, which extends to the proximal end of the **catheter** and which is connected, during use, to a source of a gas under pressure, such...

...can be inflated with a gas.

Structural balloon 22 is connected through a separate inflation **lumen** (also not shown) to a source of a liquid such as isotonic saline solution, so...

...to-rearward axis 26.

Emitter 23 is cylindrical and is coaxial with the balloons.

A **tube** 28 extends through the structural balloon at the central axis 26. **Tube** 28 defines a port 29 on or forward of the forward wall 38 of the structural balloon. **Tube** 28 communicates with a **lumen** 30 within **catheter** 12. **Lumen** 30 extends to the proximal end 14 of the **catheter** and is provided with a suitable fluid connection such as a Luer hub. The bore of **tube** 28 and **lumen** 30 of **catheter** 16 form a continuous passageway extending from the outlet port 29, just distal to the ablation device back to the proximal end 14 of the

- 15

**catheter**. As further described in co-pending, commonly

assigned U.S. Patent Application Serial No. 10/244,271, filed September 16, 2002, the disclosure of which is incorporated by reference herein, **tube** 28 may be formed from a material such as an expanded polymer of the type commonly used in vascular grafts, so that the interior bore of the **tube** remains patent when the **tube** is stretched. As also disclosed in the 1271 application, a coil spring 34 may be provided within the structural balloon, such that the coil spring surrounds **tube** 28. A reinforcing structure which may include one or more rigid **tubes** of metal or a rigid polymer such as polyether ether ketone ("PEEK") 36 desirably surrounds **tube** 28 and spring 34.

As described in greater detail in the 1271 application, the spring...

...1) relative to the rearward or proximal end of the balloon and relative to the **catheter** 12, thereby collapsing the balloon in a radial direction, and also twists the balloons about...

...element 36 engages a rigid mounting 40 attached to the distal end 16 of the **catheter**, which mounting also holds ultrasonic emitter 23. This assures that the axis 26 of the...

...the structural balloon encircling axis 26. The focused ultrasonic waves in this region can effectively **ablate myocardial** tissue and form a substantial conduction block extending through the heart wall in a relatively short time, typically about a minute or less.

In a **method** according to one aspect of the present invention, the apparatus is positioned within a chamber...

...a subject to be treated. A guide sheath (not shown) is advanced through the venous **system** into the right atrium and through the septum separating the right atrium and left atrium...

...balloons in a deflated condition. The threading operation may be performed by first threading a **guide wire** (not shown) into the heart, then advancing the guide sheath (not shown) over the **guide wire**, and then advancing the insertable structure 10, with the balloons in a deflated condition, over the **guide wire**, and through the guide sheath. In this operation, the **guide wire** passes through **tube** 28 and through **lumen** 30. When the apparatus is positioned within the heart so as to place the ablation...

...use of a contrast medium such as an x-ray contrast medium.

After threading, the **guide wire** may be removed and **lumen** 30 may be connected, as by Luer fitting 32 to a source 44 of an through **lumen** 30 and passes through the bore of **tube** 28 and out through port 29 at the forward wall 38 of the structural balloon...

...the contrast medium is injected and during spread of the contrast medium into the left **atrium**, the patient is imaged using an x-ray imaging modality, most preferably a fluoroscope.

This...

...ultrasonic waves  
and ablate the tissue of the heart wall.

In a variant of the **procedure** discussed above, a thin, tubular stylet 50 (FIG. 2) having an outlet port at its distal 35 end 52 is threaded through the continuous passageway defined by - 18

**lumen** 30 and by the bore of **tube** 28, so that the distal end 52 of the stylet projects forwardly to the distal...

...turn, is connected  
to the contrast medium source 44. Stylet 50 may serve as the **guide wire** used in threading the assembly into the patient.

Thus, stylet 50 may be placed prior to **catheter** 12 and ablation device 18. In this case, the connection at proximal end 54 may incorporate a removable hub so that the **catheter** and ablation device assembly may be threaded over the stylet and then, after the **catheter** is in place, hub 56 may be added to the proximal end of the stylet. Alternatively, the assembly may be threaded using a conventional **guide wire** which is then removed and replaced by the stylet. The stylet 50 may be relatively...

...allowing the  
physician to confirm proper position of the device.

In a further variant, a **guide wire** having an outside diameter smaller than the inside diameter of the **catheter lumen** 30 and smaller than **tube** 28 may be left in place while contrast medium is introduced through the continuous passageway defined - 19

by the **lumen** and **tube**. Because the **guide wire** does not completely occlude the passageway, the contrast medium can flow through the passageway and...

...the  
manner discussed above with reference to FIG. 1.

In yet another variant of the **procedures** discussed above, the ablation device 18 may be positioned so that the distal wall 38...

...vein and ostium and adjacent  
structures with a minimal amount of contrast medium.

Optionally, the **catheter** and ablation device may be retracted after acquiring an image of the ostium and vein...

...flow into the atrium, and further images may  
be acquired.

A significant advantage of the **procedures** discussed above with reference to FIGS. 1 and 2 is that disposition of the ablation...

...aqueous liquids.

There is no need to move any portion of the ablation device or

**catheter** during introduction of the contrast medium and visualization.

As also shown in FIG. 2, positioning...

...a range of motion as, for example, through the range between disposition indicated in solid lines by axis 24 and the disposition indicated in broken lines by axis 241. To that end, the assembly can be provided with one or more devices for selectively varying the curvature of a bendable region 60 of the **catheter** just proximal to the ablation device.

In one embodiment, shown schematically in FIGS. 3 and 4, the **catheter** is provided with one or more pull wires 64. Each such pull wire extends from the proximal end 14 of the **catheter** in a bore or lumen 66 dimensioned to provide a free-running fit for the pull wire. Each pull wire has a distal end 68 fastened to the **catheter** wall. The distal ends of the pull wires are disposed at or distal to the...

...a single pull wire is provided to provide bending in only a single direction. The **catheter** itself, or at least the  
- 21  
bendable region 60, may be resilient so that it...

...only a single plane provides considerable ability to position the ablation device. For example, the **catheter** may be "torqueable" or arranged to transmit rotation in the direction around the central axis 70 of the **catheter** itself. In such an arrangement, combined bending of region 60 and rotation of the **catheter** about its own axis 70 allows movement of the forward-to-rearward axis of the ablation device towards essentially any desired disposition.

The lumens 66 containing the pull wires 64 may be provided with coil springs (not shown) lining the lumens, so that each pull wire extends through the interior of one such coil spring.

The turns of each coil spring form a low-friction liner within the associated lumen. Moreover, the coil springs can provide additional structural reinforcement and resilience to the **catheter**.

In a variant of this approach, the bendable section 160 of the **catheter** is attached to one or more pull wires 164 which extend outside of the **catheter** at the bendable section itself.

Each such pull wire may extend through a bore 165 in the **catheter** proximal to the bendable section. By pulling on wire 164, the bendable section can be deformed to the bent configuration shown in broken lines at 1601. In this configuration, the pull wire 164 extends as a chord 1641 across...

...directions, or else a single pull wire can be used in conjunction with a torqueable **catheter** which can be rotated about its own axis by turning the proximal end of the **catheter**.

In a further variant, the pull wires may extend entirely

outside of the **catheter** . For example, where a guide sheath surrounds the **catheter** proximal to the bendable section, pull  
- 22

wires may extend within the guide sheath. In...

...the pull wires can be attached to the ablation device itself, rather than to the **catheter** . In yet another variant, the pull wires may serve as electrical conductors for energizing the...

...imaging devices and other electronic components mounted on or near the distal end of the **catheter** .

As seen in FIG. 6, the bendable section 260 of the **catheter** may be selectively deformed to the curved shape illustrated in solid **lines** by advancing a stylet 261 having a predetermined curvature through the **lumen** 230 of the **catheter** .

The stylet may be formed from a metal or plastic and may be solid or...

...as to leave a space for introduction of the contrast medium as described above through **lumen** 230. The stylet may have different properties at different points along its length. Thus, the...

...positioned so that the curved section 261 is located in the bendable region of the **catheter** . Prior to introduction of the stylet, the physician may deform curved section 261 to provide...  
...properly with the heart, and the stylet may be curved accordingly and introduced into the **catheter** . Following introduction of the stylet, the imaging **procedure** can be repeated to check for proper  
- 23

placement. Desirably, the curved section 261 of...

...straightened during threading, as the curved section is advanced from the proximal end of the **catheter** to the bendable section. Those sections of the **catheter** proximal to the bendable section desirably are more rigid than the bendable section. Thus, the...

...thickness or be formed from a more flexible material than the proximal portions of the **catheter** .

Also, the proximal portions of the **catheter** may be encased in a guide sheath 267, which terminates proximal to the bendable section...

...sheath 367 having a selected curvature is advanced over the bendable section 360 of the **catheter** so as to deform the bendable section from a straight or other configuration 3601, shown in broken **lines** , to a curved configuration, as shown in solid **lines** , having the selected curvature matching the curvature of the sheath. Sheath 367 extends to the proximal end of the **catheter** (not shown) so that the sheath can be manipulated while the device is in place...

...degree of curvature of bendable section 360. In

another embodiment, the bendable section of the **catheter** may be resilient and may be curved when in its normal or un-stressed condition...

...applied. The bendable section can be straightened during threading through the guide sheath. As the **catheter** is advanced so that the bendable section protrudes beyond the guide sheath, the bendable section returns to its normal condition. The amount of curvature can be increased by advancing the **catheter** distally relative to the guide sheath, or decreased by retracting the **catheter**. The **catheter** or guide **wire** also may incorporate a shape memory alloy such as **Nitinol** (trademark) which tends to assume a predetermined shape when heated to body temperature.

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In...

...a steerable sheath can be bent in a desired direction and used to bend the **catheter** in a desired direction. A steerable sheath may be used in conjunction with a steerable **catheter**. For example, a steerable, torqueable sheath may be used in conjunction with a steerable **catheter** having a bendable section which is constrained by the sheath and having a further bendable...

...provides a compound steering action, so that two independent bends can be imparted to the **catheter**. These bends may be in the same plane or in two different planes. In the embodiments discussed above, the **catheter** is formed separately from the guide sheath used to introduce the **catheter** into the left atrium. However, this is not essential; the functions of the **catheter** and the guide sheath may be combined. In such an arrangement, the combined guide sheath and **catheter** desirably has a distal portion bearing the ablation device and a proximal portion arranged so...

...proximal portion desirably has the strength and physical properties required for threading through the vascular **system** and through the fossa ovalis. The combined structure avoids the need to advance the expansible structure through the entire length of the guide sheath during the **procedure**.

Apparatus according to a further embodiment of the 35 invention incorporates a **catheter** having a bendable section 460

- 25

which desirably is resilient. The ablation device 418 in...

...bendable section proximal to the ablation device. Inflatable structure 402 is connected to an inflation **lumen** 404 extending within the **catheter** to the proximal end thereof. This inflation **lumen** is separate from the inflation **lumen** 406 used to inflate the reflector balloon 420 and separate from the inflation **lumen** (not shown) used to inflate structural balloon 422. With structure 402 deflated, bendable section 460...

...of the ablation device lies at an arbitrary angle to the axis 407 of the **catheter** proximal to the bendable section. However, by inflating structure 402 to the inflated condition 4021...



...to-rearward axis 4261 of the ablation device 418 with the axis 407 of the **catheter** proximal to the bendable section. Structure 402 can be inflated using a gas or a...

...to the heart. To permit selective inflation and deflation of structure 4021, the associated inflation **lumen** 404 extends to the proximal end of the **catheter** and is connected to a controllable fluid source as, for example, a syringe or other pumping device, or a tank containing fluid under pressure linked to the inflation **lumen** through a controllable pressure regulator. Bendable section 460 may be resilient so that it tends...

...402 deflated may be caused by anatomical structures bearing on the ablation device, on the **catheter**, or both. In either case, inflation of  
- 26  
structure 402 will tend to straighten the...

...further variant, the separate inflatable structure 402 may be omitted, and pressure differentials within the **lumens** of the **catheter**, such as **lumens** 404 and 406 (FIG. 8) may act to bend or straighten the **catheter**. For example, if the gas pressure in **lumen** 404 is less than the gas pressure in **lumen** 406, the **catheter** will tend to bend into a curve as depicted in FIG. B. The reverse pressure differential (higher pressure in **lumen** 404 than in **lumen** 406) will tend to straighten the **catheter** or bend it in a curve opposite to that depicted in FIG. 8. To provide a high differential pressure, one of the **lumens** may be connected to a vacuum pump whereas another **lumen** may be connected to a source of a gas or liquid under super-atmospheric pressure.

In a further modification, (FIG. 10), an inflatable structure 401 is mechanically connected between **catheter** section 461 proximal to the ablation device 418 and the ablation device itself as, for example, between the **catheter** and the proximal wall of reflector balloon 420. Thus., when inflatable structure 401 is deflated, the ablation device may be tilted relative to the **catheter**, as indicated in broken **lines** at 4181. However, when the inflatable structure 401 is inflated, as seen in solid **lines**, the ablation device is brought to the condition depicted in solid **lines**, as by bending of the **catheter** adjacent the ablation device. Here again, inflation or deflation of the inflatable structure turns the forward-to-rearward axis of the ablation device relative to the proximal regions of the **catheter** and also relative to the heart and surrounding structures.

In a further variant (FIG. 11...

...be controlled by varying the pressure within reflector balloon 420. Thus, the position of the **catheter** can be varied by varying the gas pressure applied to the reflector balloon inflation **lumen** 406. In this regard, operation of the ablation device itself does not vary significantly with...

...may  
be formed as an extension of the reflector balloon along one side of the **catheter** .  
In a further variant, seen in sectional view facing axially along the **catheter** at FIG. 12, plural inflatable structures 502 are provided around the circumference of the **catheter** 560, and the separate inflatable structures are provided with separate inflation **lumens** 504. This allows selective bending in multiple directions by controlling the gas pressures within the...

...8  
and 9, so that each structure extends only along the bendable portion of the **catheter** .

In yet another variant (FIG. 13), a plurality of inflatable structures 602 are provided around the circumference of the **catheter** and, hence, spaced around the axis 626 of the  
- 28  
ablation device 618. These inflatable...

...inflatable structure 602 is independently inflatable or deflatable as, for example, by a separate inflation **lumen** (not shown) extending to the proximal end of the **catheter** .  
Inflatable structures 602 optionally may serve as reflector balloons of the ablation device. Thus, two...

...separating walls 605 cause gaps in the ablation, this can be overcome by rotating the **catheter** so as to rotate the ablation device about axis 626 and repeating the ultrasonic application...

...it undesirable to ablate the entire ring.

Apparatus according to a further embodiment includes a **catheter** 1302 (FIG. 14) having a proximal end 1301, a distal end 1303, and an expansible...

...discussed above with reference to FIG. 1 attached to the distal  
- 29  
end of the **catheter** . As seen in FIG. 20, **catheter** 1302, at least at its distal end, includes a circular outer wall 1308, a central tubular wall 1310 defining a principal or central **lumen** 1312 and a set of webs 1314 extending between the tubular wall 1310 and the...

...wall so that the tubular wall, outer wall, and webs cooperatively define a first additional **lumen** 1316, a second additional **lumen** 1318, and a third additional **lumen** 1320 disposed in the periphery of the **catheter** , around the central **lumen** . A reinforcing structure 1321 including an emitter assembly 1322 and an extensible structure 1392 (FIG. 14) is mounted to the distal end of the **catheter** . Emitter assembly 1322 includes a proximal mounting structure 1324, a hollow, tubular piezoelectric element 1326...

...features are shown on a greatly enlarged scale in the drawings; in actual practice, the **catheter** 1302 typically has an outside diameter on the order of 3-4 mm.

As best...

...of the piezoelectric element as by soldering.

A thin-walled, electrically-conductive and preferably metallic **tube** 1370, referred to herein as the "inside **tube**," is supported by the ribs 1334 of the proximal end element, but electrically insulated from...

...for  
example, a thin coating of polymer on the exterior surface of  
- 31  
the inside **tube**. The inside **tube** extends through the interior of piezoelectric element 1326. The distal end of inside **tube** 1370 is engaged in the distal mounting structure 1328 (FIG. 21). The inside **tube** defines a bore 1374. The bore of the inside **tube** is aligned with and continuous with the bore 1350 (FIG. 18) of the distal mounting structure. The outside diameter of inside **tube** 1370 is substantially smaller than the inside diameter of the transducer element 1326.

However, the proximal and distal mounting structures maintain **tube** 1370 substantially coaxial with transducer 1326. The exterior surface of **tube** 1370 and the interior surface 1364 (FIG. 20) of the transducer 1326 cooperatively define an...

...entire emitter assembly 1322,  
including the proximal and distal mounting structures  
piezoelectric element and inside **tube** forms a rigidly connected  
unit.

The rigid transducer assembly 1322 is mounted to the distal end of the **catheter** 1302 so that the first channel 1340 in the proximal mounting structure (FIG. 16) is aligned with the first additional **lumen** 1316 of the **catheter**, whereas the second channel 1342 is aligned with the second additional **lumen** 1318 of the **catheter**. Thus, both the first and second additional **lumens** 1316 and 1318 of the **catheter** communicate with the annular passageway 1376 inside the piezoelectric element, whereas the second additional **lumen** 1318 communicates with port 1346 (FIGS. 19 and 15 and 16) through the second side channel 1342 of the proximal mounting structure. Inside **tube** 1370 is aligned with the principal **lumen** 1310 of the  
- '42

**catheter** so that the bore 1374 of the central **tube** communicates with the principal **lumen**. Slot 1344 of the proximal mounting structure is aligned with the third additional **lumen** 1320 of the **catheter**.

A small **coaxial cable** 1380 extends through the third additional **lumen** 1320 of the **catheter**. This **coaxial cable** has a first conductor in the form of a sheath 1382 and a central conductor...

...central conductor 1384 extends into the annular passageway 1376 and is bonded to the inside **tube** 1370, so that the central conductor 1384 is electrically connected by inside **tube** 1370 and distal mounting structure 1328 to the inside surface of the piezoelectric element.

A...

...wire to the proximal mounting structure 1324. , Pull wire 1385 extends through the third additional **lumen** 1320 to the proximal end 1301 of the **catheter** and is connected to a handle 1387 so that the physician can selectively pull or...

...is integrated with another handle (not shown) attached to the proximal end 1301 of the **catheter** , so that the physician can manipulate both the **catheter** and the **guide wire** . For example, the handle for the **catheter** may carry a separate knob for other manual control device so that the physician can manipulate the **catheter** by manipulating the handle and manipulate the **guide wire** by manipulating the knob or the control device.

The structural balloon 1306 (FIG. 14) is mounted on the **catheter** so that port 1346 communicates with the interior of this balloon adjacent the proximal end thereof and proximal to transducer 1326. The third additional **lumen** 1320 of the **catheter** preferably is isolated from the annular passageway 1376 and from the interior of the structural...

...For example, any portion of slot 1344, which is not occupied by portions of the **coaxial cable** 1380 extending through it may be filled with a bonding material such as an adhesive or a solder.

Third peripheral **lumen** 1320 desirably communicates with the interior of reflector balloon 1304 (FIG. 14) through an opening (not shown) in the peripheral wall 1308 of the **catheter** .

The structural balloon 1306 has a distal end fitting 1388. An extensible structure 1392 extends...also communicates with the exterior of the fitting.

Extensible structure 1392 includes a supple, distensible **tube** 1394 having its distal end connected to the distal end fitting 1388 and having its proximal end connected to emitter assembly 1322. In the arrangement shown, the proximal end of **tube** 1394 envelops the exterior of skirt 1360 on the distal mounting structure 1328. The extensible structure also includes a first engagement element in the form of a reinforcing **tube** 1396 fastened to the distal end fitting 1388 and having a bore 1398 communicating with the outlet port opening 1390. The extensible structure 1392 further includes a proximal reinforcing **tube** 1400. The proximal end **tube** 1400 is fixed in the seat 1362 of the distal mounting structure 1398.

The proximal reinforcing **tube** , and emitter assembly 1322 cooperatively constitute a second engagement element. As seen in FIG. 22, there is clearance between the outside surface of proximal reinforcing **tube** 1400 and skirt 1360 adjacent the open distal end of the conical seat 1362. The distal end of proximal reinforcing **tube** 1400 is telescopically received within the bore 1398 of the distal reinforcing **tube** 1396.

As shown in FIG. 22A, the distal end of proximal reinforcing tube 1400 has a small flange 1397 projecting outwardly, whereas the proximal end of distal reinforcing tube 1396 has a small inwardly-directed flange 1401. These features interlock with one another so that the reinforcing tubes cannot be disengaged from one another.

As will be appreciated with reference to FIG. 22...

...the bore of distal end fitting 1380, through the bore 1398 of the distal reinforcing tube, through the bore 1402 of the proximal reinforcing tube and the bore 1350 of distal mounting structure 1350 into the bore 1374 of the inside tube 1370, which in turn communicates with the central, principal lumen 1312 of the catheter. As the principal lumen of the catheter extends to the proximal end 1301 of the catheter (FIG. 14), the structure provides a continuous passageway from the proximal end of the catheter through the emitter and balloon structures through the outlet port opening 1390 on the distal...

...balloon 1306 and from the annular passageway 1376 inside the piezoelectric element 1326. The distensible tube 1394 blocks any leakage between the telescoping reinforcing tubes 1396 and 1400.

A coil spring 1406 surrounds the reinforcing tubes. The distal end of the coil spring bears on the distal end fitting 1388 and...

...assembly 1322. In this condition, also referred to as a disengaged condition, the distal reinforcing tube 1396 remote from the seat 1362 of the emitter assembly 1322. Also, the distal reinforcing tube covers only a small portion of the proximal reinforcing tube 1400. In this condition, the extensible structure 1392 can flex to a significant degree. The reinforcing tubes 1396 and 1394 are thin-walled structures. These tubes desirably have outside diameters on the order of 1-2 mm. Moreover, the tapered seat 1362 does not appreciably restrict flexing of the proximal reinforcing tube 1400. Further, there is a slight clearance between the outside of flange 1397 on proximal tube 1400 and the inside of distal tube 1396, which contributes to flexibility of the assembly. To further increase the flexibility of the assembly, the reinforcing tubes may have openings such as slots or holes in their walls.

In the deflated condition...

...gently around the extensible structure 1392 emitter assembly 1322 and the distal end of the catheter 1302.

Thus, all of the structures at the distal end of the catheter form a slender assembly capable of passing through a bore of about 0.187 inches...

...flexibility of the extensible structure. However, the extensible structure, and particularly the telescoped

- 36

reinforcing tubes are substantially resistant to kinking. The

**catheter** is also flexible. The entire assembly can be advanced and placed into a chamber of the heart, typically the left atrium in the manner discussed above. A **guide wire** (not shown) 5 may be placed through the aforementioned continuous passageway including the central **lumen** of the **catheter** and the bores 1374, 1402, and 1398 of the aforementioned **tubes**, so that the **guide wire** extends out through the outlet bore 1390 at the distal end of the assembly.

The **catheter** and associated elements are used in cooperation with operating apparatus including a liquid supply unit...

...a cool liquid under pressure and a liquid drain 1412 connected to the second peripheral **lumen** 1318 of the **catheter** at its proximal end. The liquid supply 1410, liquid drain 1412, or both desirably are...

...a throttling valve 1414 and a pressure gauge 1416 on the connection between the second **lumen** and the drain. The operating apparatus further includes a gas supply 1418 connected to the third peripheral **lumen** 1320, and a source 1419 of a contrast medium arranged for connection to the central **lumen** 1312. The operating apparatus also includes an ultrasonic actuator 1420 arranged to apply electrical energy at an ultrasonic frequency through the **coaxial cable**. The **catheter** has appropriate fittings (not shown) at its proximal end 1301 for making the connections to the operating apparatus.

Typically, the **catheter** is provided as a disposable unit, whereas some or all of the elements of the operating apparatus are provided as a reusable unit.

Prior to insertion into a patient, the **catheter** and associated elements desirably are tested by actuating the liquid supply 1410 to pass the liquid through the first peripheral **lumen** and into the structural balloon 1306.

Although some of the liquid will pass out of the structure balloon through the second peripheral **lumen** 1318, there is sufficient resistance to flow provided by the second **lumen** as well as throttling valve 1414 that the structure balloon fully inflates. As the...

...forward to rearward axis 1426. This twists the spring 1406 about axis 1426. Distal reinforcing **tube** 1396 slides rearwardly or proximally over the proximal reinforcing **tube** 1400, whereas the extensible **tube** 1394 collapses axially.

In the fully inflated condition (FIG. 23), the reinforcing **tubes** and associated elements are in an engaged condition. In this engaged condition, distal reinforcing **tube** 1396 almost entirely encompasses the proximal reinforcing **tube** 1400. The **tubes** nested in this manner are quite rigid. The reinforcing **tubes** span a substantially shorter length in this condition, and structurally reinforce one another over substantially...

...condition, any angular displacement permitted by the mutual clearance between the

exterior of the proximal **tube** and the interior of the distal **tube** is minimized. Additionally, in the engaged condition, the proximal end of distal reinforcing **tube** 1396, is firmly engaged in the tapered, conical seat 1362 of the distal mounting structure 1328 on the emitter assembly 1322. This locks the telescoped **tubes** firmly in position relative to the emitter assembly. in this condition, the reinforcing structure 1321...

...FIG. 14) and the  
..WO 2004/073505 PCT/US2004/005197  
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adjacent regions of the **catheter** 1302. In this engaged condition, the distal or forward end of the expansible structure is...

...structure and relative to the emitter assembly.

The flowing liquid passes from the first peripheral **lumen** through the first channel 1340 of the proximal mounting structure and into the annular passageway...

...1346, a second channel 1342 of the proximal mounting structure 1324 and the second peripheral **lumen** 1318. This **process** is continued for a sufficient time to sweep out air or other gases...

...1420 is operated to supply electrical energy to ultrasonic element 1326 by way of the **coaxial cable** 1380 (FIGS. 19 and 20). This allows a final test of the electrical connections and...

...resonant of frequency of the piezoelectric element 1326. Different piezoelectric elements incorporated carried by different **catheters** will have slightly different resonant frequencies. The resonant frequency of the piezoelectric element 1326 may...

...are completely filled by substantially gas-free liquid.

After testing, the distal end of the **catheter** is advanced through the patient's vascular **system**, with the balloon structure in the collapsed or deflated condition, so as to position the...

...device in the deflated condition, and the relatively small diameter of the device, facilitates this **process**. A **guide wire** (not shown) can be inserted through the continuous passageway and through the distal outlet port 1390 during this **process**. The **guide wire** may be removed after ablation device is advanced into the heart chamber.

Once the **catheter** is located in the heart chamber, the balloon structure is brought to its inflated condition...

...structure and with the central axis 1426.

By manipulating the pull wire 1385 and the **catheter**, the physician can position the ablation device, including the balloons and ultrasonic emitter in a...

...thus swing axis 1426. This turning motion is accompanied by bending of those portions of **catheter** 1302 near the distal end of the **catheter**. Because the pull wire is connected to the rigid reinforcing structure itself, at a point...

...chamber. By contrast, in an otherwise comparable device where the pull wire is affixed to **catheter** proximal to the expansible structure, the expansible structure will tend to swing about a pivot...

...it provides an additional safety feature. In the event of a structural failure in the **catheter** or balloons, the emitter assembly and those portions of the **catheter** and balloons remaining attached to the emitter assembly can be retrieved from within the patient...

...the pull wire until the same can be surgically removed in an emergency open-heart **procedure**. Further, the distal end fitting 1388 is connected to the emitter assembly by the welded spring 1406 and by the interlocked flanges 1397 and 1401 on the reinforcing **tubes** 1396 and 1400 (FIG. 22A). Thus, despite the failure of any other structural elements, distal...

...of the emitter assembly 1322.

In the manner discussed above, the physician can rotate the **catheter** and thus rotate the expansible structure and the pivot axis 1430 about the central axis 1426. Therefore, by adjusting the pull wire and rotating the **catheter**, the physician can bring the expansible structure and the central axis to essentially any desired...

...using a contrast medium injected from contrast medium supply 1419 (FIG. 14). To form a **lesion** in the form of a complete loop or a substantial portion of a loop, the...

...piezoelectric element and cause the device to emit ultrasonic waves and ablate a loop-like **lesion** L in the heart wall, encompassing all or a substantial portion of a loop extending around the axis 1426. As mentioned above, such a loop-like **lesion** can be formed around the ostium OS of a pulmonary vein or around another anatomical...

...focal region A is within or in close proximity to the heart wall. Thus, a **lesion** LI will be formed only along a relatively small arcuate region approximating a straight line.

The energy directed into other portions of the ablation region A1, which lie remote from...

...the device and the pulmonary vein ostium or other anatomical structures, the loop-like and **linear lesions** can be placed where desired.



It has been proposed that atrial **fibrillation** can be treated successfully by forming **lesions** surrounding the ostia of the pulmonary veins in combination with **linear lesions**. Such a combination of **lesions** can be achieved by use of the canted and normal dispositions. Preferably, the ablation device...

...contrast medium while the balloons remain in their inflated condition, and without using a separate **catheter** for such introduction, is advantageous.

When the piezoelectric element is actuated to emit ultrasonic waves...

...of the structural balloon, the aqueous liquid passes from the supply 1410 through first side **lumen** 1316 of the **catheter**, through the first channel 1340 of the proximal mounting structure and into the annular channel...

...1346 (FIG. 21), second channel 1342 of the proximal mounting structure and the second peripheral **lumen** 1318 of the **catheter**, whereupon it passes to the drain. This circulation is achieved without need for a separate **catheter** for liquid circulation and without occupying the central **lumen** of the **catheter** with the circulating liquid.

The circulating liquid effectively removes heat from the piezoelectric element.

- 45...

...the variant depicted in FIGS. 25 and 26, the extensible structure 1492 includes a reinforcing **tube** 1496 which can be telescopically received inside the emitter assembly 13221 when the expansible structure...

...13061 is in its inflated condition (FIG. 26). In the particular structure illustrated, the reinforcing **tube** 1496 fits through the bore 1450 of the distal mounting structure of the emitter assembly and is telescopically received within the inside **tube** 1370. When the expansible structure is collapsed, and hence balloon 1306, is deflated, the reinforcing **tube** 1496 is partially or fully withdrawn from the inside **tube** 13701, from bore 1450, or both. Here again, the structure provides reinforcement against kinking, but...

...proximal element. In this engaged condition, the elements form a rigid reinforcing structure. An extensible **tube** may extend from the proximal element through the interior of the coil spring, so as...

...the proximal mounting structure discussed above. Also, it is not essential that the second peripheral **lumen** of the **catheter** communicate with the interior of the structural balloon through a feature of the proximal mounting structure. For example, where the distal end of the **catheter** projects into the interior of the structural balloon, the **catheter** itself may be provided with a port or slots to provide communication with the second **lumen**. In a further variant, one or both of the mounting structures may be omitted. For

example, the proximal mounting structure may be omitted if the distal end of the **catheter** itself incorporates a port. In such an arrangement, one of the additional **lumens** of the **catheter** may communicate directly with the interior of the tubular piezoelectric element, whereas another additional **lumen** of the **catheter** may communicate directly with the interior of the structural balloon. Also, although it is highly...

...same can be omitted as,  
for example where it is acceptable to use a separate **catheter** for injection of the contrast medium. Also, although the reinforcing structure 1321 discussed above provides...

...the embodiment discussed above with reference to FIGS.

14-23, the interface between the inside **tube** 1370 and the 35 liquid in the annular passageway 1376 has some reflectivity for - 48...

...hereby incorporated by reference herein, a highly reflective interface may be provided by forming a **tube** as a dual-walled structure with an gas-filled space between the walls.

Further, certain...

...can be deformed in any of the ways discussed above with reference to deforming the **catheter**, so that the disposition of the ablation device relative to the heart wall W may...

...controlled as, for example, by bending the link 703 to the position indicated in broken **lines** at position 7031, so as to move the ablation device to the position indicated in broken **lines** at 7181. The guide element 701 or the link 703 may be provided with a...be used in conjunction with the other positioning systems discussed herein. However, where a steering **system** is provided for controlling the disposition of the ablation device, it is desirable to omit...

...I  
oni ame  
Balloon length (LB) 35.0000  
mm  
Balloon radius (RB) 16.0000  
mm  
**Lumen** radius (RL) 1.6890 mm  
Parabola focus (PFH) 27.0000  
height mm  
Parabola focus (PFR....

...thereby direct the ultrasonic waves into a first loop-like region A, shown in solid **lines**, or onto a second region A1 of larger diameter, shown in broken **lines**.

Alternatively, an elongated emitter may be provided in two independently actuatable zones so that when...

...to ablation of ring-like region. For example, as seen as FIG. 37 an elongated **catheter** 1200 has gas filled regions 1202 and 1204 and a liquid-filled region 1206

extending lengthwise along the **catheter** . Gas-filled region 1202 defines a first reflective interface 1208 with the liquid filled region...

...liquid-filled region

- 57

disposed between the converging interfaces extends to the exterior of the **catheter** and defines an exit window 1212.

Thus, the reflective interfaces define a channel 1251 having...  
...window is generally in the form of a strip or slit extending lengthwise along the **catheter** . A planar, slab like transducer 1214 also extends lengthwise along the **catheter** . As seen in FIG. 37, ultrasonic waves directed from the face of the planar transducer...

...example, to ablate a strip-like region of tissue.

In yet another embodiment, an elongated **catheter** 1300 (FIG. 38) includes a central **lumen** 1302 filled with a liquid.

The **catheter** includes an outer sheath 1304 surrounding the central **lumen** and defining an annular space 1306 between the wall 1308 of the central **lumen** and the exterior of the **catheter** . The space 1306 is filled with a gas so as to define a single tubular reflective interface at the wall 1308 of the central **lumen** , forming a tubular channel. Such a **catheter** serves as a flexible wave guide for ultrasonic waves. The reflective interface 1308 may also...

...As discussed above, in ablation of the heart wall for treatment of atrial fibrillation, the **ablation** region desirably extends through the heart wall, rather than through the wall of the pulmonary...

...the pulmonary vein and at as large a diameter as possible, so as to minimize **scarring** and stenosis of the pulmonary vein.

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Imaging modalities other than fluoroscopy can be...

...devices other than the specific balloon

5 structures discussed above can be used. Also, the **techniques** can be used with non-ultrasonic ablation devices.

As discussed in the aforementioned co-pending applications, the **techniques** used for pulmonary vein ablation also can be applied to ablation of other anatomical structures...

#### Claim

1. Apparatus for performing **cardiac ablation** in a mammalian subject comprising:

(a) an insertable structure, said insertable structure including:

(i) a **catheter** having proximal and distal ends; and

(ii) an ablation device mounted to the **catheter** adjacent the distal end thereof , said ablation device being adapted for placement within a chamber of the heart

of a mammalian subject and adapted to **ablate** a region of the cardiac structure bounding such chamber when the **ablation** device is in an operative configuration, said insertable structure defining an outlet port 15 open...

...the ablation device and a continuous passageway extending from adjacent said proximal end of said **catheter** to said outlet port; and  
(b) a source of a contrast medium adapted for connection...  
...device is in said operative configuration.

2 Apparatus as claimed in claim 1 wherein said **catheter** has a **lumen**, said **lumen** forms at least a part of said continuous passageway and wherein said source of contrast medium is adapted for connection to said **lumen** adjacent the proximal end of the **catheter**.

3 Apparatus as claimed in claim 1 wherein said insertable structure further includes a hollow stylet, said stylet being adapted to extend through said **catheter** and said ablation device while said ablation device is in said operative condition, said source...

...for directing emitted ultrasonic waves from said emitter generally in the distal direction.

7 A **method** of performing **cardiac** ablation comprising:  
(a) providing an **ablation** device in a chamber of the heart of a mammalian subject such that the device...  
...operative configuration with a distal side of the device facing toward a region of the **cardiac** structure to be ablated; and  
(b) while the **ablation** device is in said operative configuration, injecting a contrast medium into said chamber on the distal side of said ablation device.

8 A **method** as claimed in claim 7 further comprising obtaining one or more images depicting said contrast medium in at least a portion of the cardiac structure.

9 A **method** as claimed in claim 8 wherein said contrast medium is an x-ray contrast medium and said step of obtaining said images is performed by x-ray imaging.

10 A **method** as claimed in claim 8 wherein said chamber of the heart is the left...

...medium and obtaining images are performed so that said images show contrast medium in the **atrium** and in at least one pulmonary vein.

11 Apparatus for performing cardiac ablation in the heart of a mammalian subject comprising:  
(a) a catheter;  
(b) an ultrasonic **ablation** device having a forward-to-rearward axis, said ultrasonic ablation device being adapted to emit...

...61

region surrounding said forward to rearward axis, said ablation device being mounted to said **catheter** ; and  
(c) a steering **system** adapted to selectively vary the disposition of the forward-to-rearward axis of the ultrasonic...

...includes an expansible structure having a collapsed, inoperative state and an expanded, state, said steering **system** being operative to selectively vary said disposition while said expansible structure is in said expanded...

...in claim 12 wherein said expansible structure includes at least one balloon and said steering **system** is operative to selectively vary said disposition while said at least one balloon is in...

...is in said expanded condition.

15 Apparatus as claimed in claim 14 wherein said steering **system** includes at least one pull wire mechanically connected to said reinforcing structure adjacent the proximal end thereof.

16 Apparatus as claimed in claim 11 wherein said steering **system** is operative to move the balloon between a

- 62  
normal disposition in which said forward...

...propagation having a forward component.

19 Apparatus as claimed in claim 11 wherein said steering **system** is operative to selectively vary the disposition of said ultrasonic ablation device independently of engagement...

...ultrasonic ablation device and the heart.

20 Apparatus as claimed in claim 11 wherein said **catheter** has proximal and distal ends and a bendable section proximal to the ablation device, said steering **system** being operative to selectively bend the bendable section of the **catheter** .

21 Apparatus as claimed in claim 11 further comprising a guide element adapted to engage a portion of the heart or vascular structure adjacent the heart, said steering **system** being operative to vary the disposition of the ultrasonic ablation device relative to the guide...

...to the ultrasonic ablation device.

23 Apparatus as claimed in claim 11 wherein said steering **system** includes at least one inflatable structure

- 63  
mechanically connected to said ultrasonic ablation device or to said **catheter** , said at least one inflatable structure being arranged such that inflation or deflation...

...alter the disposition of the

5 ultrasonic ablation device, and one or more inflation lumens connected to said inflatable structures so that said at least one inflatable structures can...

...23 wherein at least one said inflatable structure extends along said bendable region of the **catheter** the so that inflation or deflation of such structure tends to change the curvature of...

...said at least one inflatable structure includes parts of said plural reflector balloons.

29 A **method** of cardiac ablation in a mammalian subject comprising the steps of:

(a) advancing apparatus including a catheter bearing an ultrasonic **ablation** device into the subject until the ultrasonic ablation device is within a chamber of the...

...disposition of the forward-to-rearward axis of the ultrasonic ablation device relative to the **catheter** ;

(c) while the ultrasonic ablation device is in said first disposition, ablating the heart wall to form a first **lesion** by actuating the ultrasonic ablation device to direct ultrasonic waves into at least a portion...

...device; and then

(d) removing the ultrasonic ablation device from the subject.

30 . A **method** as claimed in claim 29 further comprising the steps of

(e) repositioning the ultrasonic ablation...

...within the

chamber by further selectively varying the disposition of said axis relative to the **catheter** ; and

(f) while the ultrasonic ablation device is in said second disposition, ablating the heart wall to form a second **lesion** by actuating said ultrasonic ablation device to direct ultrasonic waves into said loop-like region...

...to said step (d), while the ultrasonic ablation device remains within said chamber.

31 A **method** as claimed in claim 30 wherein at least one of said dispositions is a normal...

...steps is

performed while said ablating device is in said normal disposition so form a **lesion** in the shape of at least a major portion of a loop.

32 A **method** as claimed in claim 31 wherein at least one of said dispositions is a canted...

...steps is performed while said ablating device is in said canted disposition so form a **lesion** in a generally **linear** shape.

33 A **method** as claimed in claim 32 wherein, during both of said ablating steps, said ablation device directs said

ultrasonic waves into the entirety of said loop-like region,

34 A **method** as claimed in claim 33 wherein, during each said ablation step, said ablation device focuses...

...to said region and

decreases in said direction of propagation beyond said region.

35 A **method** as claimed in claim 34 wherein said direction of propagation has a component in a forward direction parallel to said axis.

36 A **method** as claimed in claim 32 wherein said chamber is the left **atrium** and said positioning step is performed so that at least a portion of said loop-like **ablation** region lies in a portion of the heart wall defining or surrounding the ostium or ostia of one or more pulmonary veins.

37 A **method** as claimed in claim 32 further comprising imaging at least a portion of the chamber...

...and conducting said positioning

step based at least in part on said imaging.

38 A **method** as claimed in claim 29 wherein said positioning step is performed independently of mechanical engagement between an element of the apparatus distal to the ultrasonic **ablation** device and the anatomy.

39 A method as claimed in claim 29 said chamber is the left **atrium** and said positioning step is performed independently of any mechanical engagement the apparatus and a...

...including:

(i) a tubular piezoelectric element having proximal and distal ends; and

(ii) a inside **tube** extending within said tubular piezoelectric element so that said inside **tube** and said piezoelectric element cooperatively define an annular passageway extending between said proximal and distal ends of the piezoelectric element, said **tube** defining a **tube** bore;

(b) a balloon surrounding said emitter, said balloon having an interior space, said annular...

...the interior of said balloon adjacent the distal end of said emitter assembly;

(c) a **catheter** having proximal and distal ends, said **catheter** having a principal **lumen** and first and second additional **lumens** ;

(d) said principal **lumen** communicating with said **tube** bore, said first additional **lumen** communicating with the proximal end of said annular passageway and said second additional **lumen** communicating with the interior of said balloon adjacent the proximal end of said emitter assembly...

...includes a proximal mounting structure disposed at least partially between the distal end of the **catheter** and the proximal end of the tubular piezoelectric element, said proximal mounting structure at least...

...defining a port communicating with the interior of said balloon, a central bore connecting said **tube** bore with said principal **lumen** of said **catheter**, a first side channel connecting said first additional **lumen** of said **catheter** with said annular passageway and a second side channel connecting said second additional **lumen** of said **catheter** with said port so that the second additional

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**lumen** communicates with the interior of the balloon through said port.

42 Apparatus as claimed in...

...are at least partially electrically conductive, the apparatus further and electrical conductors extending within said **catheter**, one of said conductors being electrically connected to said proximal mounting structure, another one of...

...surface.

45 Apparatus as claimed in claim 44 wherein at least a portion of said **tube** is electrically conductive; the apparatus further comprising electrical insulation disposed between said **tube** and said proximal mounting structure, one of said electrical conductors being electrically connected to said distal mounting structure by way of said **tube**.

46 Apparatus as claimed in claim 41 wherein said balloon has a distal end distal...

...extensible element

defining a passage connecting said outlet port to said bore of said inside **tube** so that said extensible element, said inside **tube** and said principal **lumen** cooperatively constitute a continuous passageway.

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47 Apparatus as claimed in claim 46 wherein said extensible element includes a distensible **tube** having a proximal end attached to said emitter assembly and having a distal end attached...

...48 Apparatus as claimed in claim 46 wherein said extensible element includes a distal reinforcing **tube** connected to said balloon adjacent the distal end thereof and a proximal reinforcing **tube** connected to said emitter assembly, said reinforcing **tubes** being telescopically engaged with one another.

49 Apparatus as claimed in claim 48 wherein said emitter assembly includes a distal end element, said distal reinforcing **tube** engaging said distal end element when said balloon is in an inflated condition, said distal reinforcing **tube** being disengaged from said distal end element but remaining telescopically engaged with said proximal reinforcing **tube** when said balloon is in a deflated condition.

So. Apparatus comprising:

- (a) a **catheter** having proximal and distal ends;
- (b) an expansible structure mounted to said **catheter** adjacent the distal end thereof, said expansible structure having proximal and distal ends, an expanded...



...50 further comprising a pull wire extending between the proximal and distal ends of the **catheter**, said pull wire being attached to said second engagement element.

53 Apparatus as claimed in...

...said engagement elements is telescopically received in another one of said engagement elements.

54 Ultrasonic **ablation** apparatus for ablating a region of the **cardiac** structure adjacent an ostium of a blood vessel extending to or from the heart comprising:

- (a) a **catheter** having proximal and distal ends;
- (b) an ultrasonic ablation device mounted to said **catheter** adjacent the distal end thereof, said ultrasonic ablation device said ablation device being adapted for...

...structure encircling said forward to rearward axis rearwardly of the device.

55 A method of **cardiac ablation** comprising the steps of:

- (a) positioning an **ablation** device within a blood vessel extending to or from the heart so that a
- 70...

...portion of a ring-like region encircling the axis rearwardly of the device.

56 A **method** as claimed in claim q5 wherein said blood vessel is a pulmonary vein and said ring-like region is disposed in the ostium of the pulmonary vein or in the **cardiac** wall encircling the ostium.

57 Apparatus for ablating the **cardiac** wall surrounding one or more pulmonary veins comprising an ultrasonic emitter arranged to emit ultrasonic...

...a ring-like region having a diameter between 28 and 38 mm.

58 Apparatus for **ablating** the **cardiac** wall comprising an ultrasonic emitter arranged to emit ultrasonic waves directed outwardly from a forward...

...wherein said reflector includes one or more balloons defining said active regions.

64 Apparatus for **cardiac ablation** comprising:

- (a) an expansible reflector surrounding a forward-to-rearward axis; and
- (b) an ultrasonic...

...form of an exponential curve.

76 Apparatus as claimed in claim 68 further comprising a **catheter** having proximal and distal ends, said emitter and said

inflatable structure being mounted to said **catheter** adjacent said distal end.

77 Ultrasonic apparatus comprising:

(a) a ultrasonic emitter having an emission...

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DIALOG(R)File 349:PCT FULLTEXT  
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*Some of the ~~inventors~~ INVENTORS*

01017867 \*\*Image available\*\*

**RADIO-FREQUENCY-BASED CATHETER SYSTEM WITH IMPROVED DEFLECTION AND STEERING MECHANISMS**

**SYSTEME DE .CATHETER A RADIOFREQUENCE AVEC MECANISMES DE DEVIATION ET DE GUIDAGE AMELIORES**

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Detailed Description  
Claims

**English Abstract**

A shapeable curvilinear radio-frequency **antenna** apparatus (110) for ablating biological tissue within the body vessel of a patient includes a flexible **catheter** body (120) having a distal portion (140) and an elongated **lumen** (150). Inner and outer coaxially aligned conductors (640, 660) extend within the **catheter** (120) and are coaxial with the **lumen** (150). A flexible shapeable **curvilinear** radio-frequency **antenna** (250) is carried by the distal portion of the flexible **catheter** body (120) and is in electrical communication with the inner and outer coaxially aligned conductors (640, 660). The flexible shapeable **curvilinear** radio-frequency **antenna** (250) is adaptable to receive and transmit radio-frequency energy for ablating biological tissue and is shapeable between a straight configuration (190) and a **curvilinear** configuration (180) for creating a **curvilinear** ablation pattern in biological tissue within the body vessel of a patient.

**French Abstract**

...un tissu biologique dans une cavite corporelle d'un patient et comprenant un corps de **catheter** souple (120) dote d'une partie distale (140) et d'une lumiere allongee (150). Des conducteurs interieur et exterieur a alignement coaxial (640, 660) se prolongent a l'interieur du **catheter** (120) et sont disposes de maniere coaxiale par rapport a la lumiere (150). Une antenne...

...curviligne deformable souple (250) est supportee au niveau de la partie distale du corps de **catheter** souple (120) et se trouve en communication electrique avec ces conducteurs interieur et exterieur a ...

#### Detailed Description

RADIO-FREQUENCY-BASED **CATHETER SYSTEM**  
WITH IMPROVED DEFLECTION AND STEERING MECHANISMS  
FIELD OF THE INVENTION  
foll The present invention relates...

...powered medical apparatus and ablation of biological tissues, and, in particular, to a RF based **catheter system** with improved deflectable and steering capabilities.

#### 0 BACKGROUND OF THE INVENTION

[02] In recent years of cardiac diseases. The first has been the shift from open-heart surgical **procedures** to less invasive and less expensive **catheter**-based treatments, which are safer and less debilitating.

[03] The second trend is represented by the shift from the use of anti **arrhythmic** drugs to minimally invasive **catheters** or other device-based therapies to palliate incurable **arrhythmias**. For example, automatic cardioverter-defibrillator are routinely implanted in patients with lethal ventricular arrhythmias to reduce the likelihood of sudden death. Thus, **radio - frequency** ( RF ") catheter ablation is now being performed in large number of patients suffering from **cardiac** arrhythmias.

[04] Despite these advances in technology, **atrial fibrillation** ("AF") remains a significant challenge. AF, a rapid irregular rhythm in the atria or upper...

...and heart attack and a major health care burden. To date, the most effective surgical **procedure** for the treatment of AF has been the Maze **procedure** undertaken in "open-heart" surgery. In the Maze **procedure**, incisions are made along pre-determined **lines** exterior of the atrium, which are then sutured together. As healing develops, **scars** lare formed along the incision **lines** thereby forming ...AF can no longer be sustained and regular heart rhythm is restored. However, the Maze **procedure** has not been widely adopted due to the cost and mortality associated with open-heart surgery, but only as adjunct to other major **procedures** such as mitral-valve replacement.

[05] One new approach to mimic the Maze operation is represented by catheter-based **radio - frequency ablation technique**, wherein,

instead of

surgical incisions, a **catheter - antenna** is applied to destroy or **ablate** the heart I O tissues inside the **atrial** chamber. The **catheter - antenna** is passed through the vein for access to the atrium, as commonly practiced in the medical field.

Within the atrium, the tip of the **catheter - antenna** is positioned, usually with the aid of x-ray or fluoroscopic means, and is brought...

...At this 1 5 spot, the tissue is destroyed by resistive heating generated from the **catheterantenna**. Thereafter, the **catheter - antenna** is re-positioned to the next spot for ablation. A series of spot ablations thus mimics the **linear lesions** as accomplished under the **Maze procedure** against the conduction of electrical impulses.

[06] Existing **catheter**-based ablation procedures are recognizably less intrusive than "open-heart" surgery. In addition, during the **ablation**, disruption of **cardiovascular** function is reduced. However, a successful catheter-based **radio - frequency ablation** procedure requires the **ablation** of tissue spots within the spatial or proximity tolerance between adjacent spots, usually less than...

...passage of electrical impulses.

In that connection, the task for the precise placement of the **catheter - antenna** represents a critical element of a successful **procedure**.

[07] A major drawback of such existing **procedures** is in the timeconsuming task in positioning the **catheter - antenna** at the desired **ablation** spots within the atrium while the heart chamber muscles are pulsating.

Movements of **atrial** wall or the heart muscles often render accurate placement of the **catheter - antenna** difficult, and slippage of the **catheter**

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**antenna** tends to occur thereby damaging portions of the **atrium** where ablation is not desired. As a result, placement of the catheter based RF **ablation** cannot be efficiently accomplished, and prolonged **procedure** time, in excess of 12 hours, can be expected. Further, during the **procedure**, x-ray or other irradiating means are routinely employed for locating and positioning the **catheter - antenna**, which dictates the use of heavy lead protective gear by the electro-physiologist. As a result, such inconvenience is often amplified by the prolonged **procedure** time, which detracts from the use of **catheterbased antenna** as an efficient means for tissue ablation.

1 0 [08] To minimize the risk of slippage, for example, in U.S. Patent No.

5,741,249, a **catheter**-based microwave antenna is disclosed wherein a distal tip is incorporated into the antenna to catheter-antenna slippage during each **ablation** step, it does not eliminate the consuming task 1 5 to secure precise placement of the **antenna** along the desired ablation path for each ablation step. Thus, after each ablation step, the **antenna** has to be re-positioned and anchored precisely at the next spot which must be...

...fibrillation with catheter ablation will require the creation of long or

overlapping linear or curvilinear **ablation** lesions on the inner surface of the **atrium** . These **lesions** can then act as barriers to the conduction of electrical impulses, thus preventing atrial fibrillation...

...ability to stabilize and anchor the catheter and microwave antenna inside the atrial chambers. New **catheter** ablation systems capable of stabilizing and anchoring the **catheter** and microwave antenna inside the atrial chambers, preferably capable of producing long or overlapping linear or curvilinear ablation lesions, are required for the development of minimally invasive **catheter** -based curative procedures for **atrial fibrillation** .

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[1 1] U.S. Patent No. 6,190,382, ...No. 09/459,058, filed December 11, 2000, disclose a radiofrequency or microwave-energy based **catheter** for ablating biological tissues within the body vessel of a patient. The **catheter** has a proximal portion, a distal portion with a distal opening and a **lumen** extending from the proximal portion to the distal portion. The **catheter** incorporates an elongated **catheter** guide that is located within the **catheter** **lumen** and is secured to the distal portion of the **catheter** at one end, with the other end portion extending proximally within the **catheter** **lumen** to be coupled to a positioning mechanism. A significant advantage of the **catheter** guide is that it is deployable beyond the distal opening of the **catheter** to form a loop, which is conformable to the interior contour of the body vessel. The **catheter** guide carries the **catheter** with a radio-frequency or microwave energy based **antenna** incorporated at the distal portion of the **catheter** . The **antenna**

1 5 includes a helical coil, which accommodates the **catheter** guide passing through it.

[12] The radio-frequency **antenna** is adapted to receive and irradiate radio frequency energy in the microwave range at a ...for ablating biological tissue along a biological ablation pathway.

#### SUMMARY OF THE INVENTION

[13] The **catheter** of the present invention provides further enhancements and features to the **catheter** described in U.S. Patent No. 6,190,382 and U.S.

patent application Serial No. 09/459,058. These improvements and features, among others, include a shapeable **antenna** , various pre-shaped **antenna** at the distal ends, tendon-type **antenna** deflecting and steering mechanisms for easy deflection, steering and manipulation of the **catheters** , and sensors for monitoring different parameters during ablation.

[14] The shapeable **antenna** of the present invention allows for precise **ablation** of body tissue, and is particularly suitable to create linear or curvilinear ablation lesions on the inner surface of the **atrium** . These **lesions**

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can then act as barriers to the conduction of electrical impulses, thus preventing atrial **fibrillation** . The shapeable **antenna** apparatus

allows the **antennas** to quickly, easily, and precisely achieve optimum position over a target tissue and maintain stability...

...tissue to bring about therapeutic effects.

[15] Another aspect of the invention involves a shapeable **curvilinear** radiofrequency **antenna** apparatus for ablating biological tissue within the body vessel of a patient. The shapeable **curvilinear** radio-frequency **antenna** apparatus includes a flexible **catheter** body having a distal portion and an elongated **lumen**. Inner and outer coaxially aligned conductors extend within the **catheter** and are coaxial with the **lumen**. A flexible shapeable **curvilinear** radio-frequency **antenna** is carried by the distal portion of the flexible **catheter** body and is in electrical communication with the inner and outer coaxially aligned conductors. The flexible shapeable **curvilinear** radio-frequency **antenna** is adaptable to receive and transmit radio-frequency energy for ablating biological tissue and is shapeable between a straight configuration and a **curvilinear** configuration for creating a **curvilinear** ablation pattern in biological tissue within the body vessel of a patient.

[16] A further aspect of the invention involves a **method** of ablating biological tissue within the body vessel of a patient. The **method** includes the steps of: providing a shapeable **curvilinear** radio-frequency **antenna** apparatus for ablating biological tissue within the body vessel of a patient, the shapeable **curvilinear** radio-frequency **antenna** apparatus including a flexible **catheter** body including a distal portion and an elongated **lumen**, inner and outer coaxially aligned conductors extending within the **catheter** and coaxial with the **lumen**; and a flexible shapeable **curvilinear** radio-frequency **antenna** carried by the distal portion of the flexible **catheter** body and in electrical communication with the inner and outer coaxially aligned conductors, the flexible shapeable **curvilinear** radio-frequency **antenna** adaptable to receive and transmit radio frequency energy for ablating biological tissue and shapeable between a straight configuration and a **curvilinear** configuration for creating a **curvilinear** ablation pattern in biological tissue within the body vessel of a patient;

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delivering the shapeable **curvilinear** radio-frequency **antenna** apparatus to a targeted body tissue ...configuration to a pre-shaped memory curvilinear configuration so that the flexible curvilinear radio-frequency **antenna** is adjacent to the body tissue to be ablated; and ablating the body tissue using the flexible shapeable **curvilinear** radio-frequency **antenna**.

[17] Further objects and advantages will be apparent to those skilled in the art after and 1 B are side-elevational views of a RF ablation **catheter** including a handle with an embodiment of a steering mechanism for steering a shapeable **antenna** apparatus of the present invention.

[19] FIGS. 2A and 2B are side-elevational views of a RF ablation **catheter** including a handle with an alternative embodiment of a steering mechanism for steering a shapeable **antenna** apparatus of the present invention.

[20] FIGS. 3A and 3B are side-sectional views of an embodiment of a shapeable **antenna** apparatus of the present invention in a straight

configuration and a shaped configuration.

[21] FIGS. 4A and 4B are side-sectional views of an alternative embodiment of a shapeable **antenna** apparatus of the present invention in a straight configuration and a shaped configuration.

[22] FIGS. 5A and 5B are side-sectional views of another embodiment of a shapeable **antenna** apparatus of the present invention in a straight configuration and a shaped configuration.

[23] FIGS. 6A and 6B are side-sectional views of a further embodiment of a shapeable **antenna** apparatus of the present invention in a straight configuration and a shaped configuration.

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[24] the deflection regulating member of the embodiments of the shapeable **antenna** apparatus illustrated in FIGS. 5A,B and 6A,B.

[25] FIG. 8 is a side-elevational view of a RF ablation **catheter** including a shapeable **antenna** apparatus constructed in accordance with another embodiment of the present invention.

[26] FIGS. 9A and 9B are side-sectional views of the shapeable **antenna** apparatus of the RF ablation **catheter** illustrated in FIG. 8.

[27] FIG. 10 is a perspective view of a radio-frequency **catheter** with deflectable and steering capabilities according to an embodiment of the present invention.

[28] FIG...1A is a partial side sectional view of the distal portion of the radio-frequency **catheter** of FIG. 10 and illustrates an embodiment of a deflectable **catheter** guide.

[29] FIG. 11B is a cross-sectional view taken along lines 11B-11B of FIG. 11A.

[30] FIG. 11C is a cross-sectional view taken along lines 11C-11C of FIG. 11A.

11A.

[31] FIG. 12A is a partial elevational view of another embodiment of a deflectable **catheter** guide where the **catheter** guide has a varying dimensioned spine.

[32] FIG. 12B is a partial top view of the same embodiment of the deflectable **catheter** guide of FIG. 12A.

[33] FIG. 12C is a cross-section view taken along lines 12C-12C of FIG. 12B.

[34] FIG. 12D is a cross-section view taken along lines 12D-12D of FIG. 12B.

[35] FIG. 13 is a partial elevational view of the deflectable **catheter** guide of FIG. 12B disposed within a **lumen** of a distal portion of the



radio-frequency **catheter** of FIG. 10.

[36] FIG. 14 is a partial elevational view of the distal portion of the radiofrequency **catheter** of FIG. ...side sectional view of an alternative embodiment of a distal portion of a radio-frequency **catheter** and shows an embodiment of a deflectable **catheter** guide with a flexible spine of a partial tubular construction and a pull wire tendon extending within a **lumen** of the flexible spine.

[38] FIG. 16 is a partial side view of the distal portion of the radiofrequency **catheter** illustrated in FIG. 15 and shows the deflectable **catheter** guide with a guide leader extending distally of the distal portion of the radiofrequency **catheter**.

[39] ...depictions of a clockwise and a counterclockwise pre-shaped distal portion of a radio-frequency **catheter**.

[40] FIGS. 18A and 18B are schematic depictions of a clockwise and a counterclockwise pre-shaped distal portion of a radio-frequency **catheter** including a pull wire to assist in shaping the distal portion.

[41] FIG. 19 is a partial side sectional view of an embodiment of a radio frequency **catheter** incorporating an embodiment of a deflectable **catheter** guide attached to a slide control for deflection and steering of the distal portion of the radio-frequency **catheter**.

[42] FIG. 20A is a partial top view of another embodiment of a deflectable **catheter** guide with bidirectional deflection capability.

[43] FIG. 20B is a partial elevational view of the same embodiment of the deflectable **catheter** guide of FIG. 20A.

[44], FIG. 20C is a cross-sectional view of the deflectable **catheter** guide of FIG. 20A taken along **lines** 20C-20C of FIG. 20A.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[45] WithreferencetoFIGS.1Aand1B,aradio-frequency("RF")ablation **catheter** 100 including a shapeable **antenna** apparatus 110 constructed in accordance with an embodiment of the present invention is shown. The **catheter** 100 is adaptable for insertion into a body vessel of patient and the shapeable **antenna** apparatus 110 includes a radio-frequency **antenna** for delivering electromagnetic energy to a treatment site. The **catheter** 100 will

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first be described before describing the shapeable **antenna** apparatus of the present invention.

[46] The **catheter** 100 has a flexible elongated tubular body 120 with a proximal portion 130 and...

...more intracavity

lurnens 150 (FIGS. 3A, 313) extend from the proximal portion 130 of the **catheter** 100 to the distal portion 140. Located at the proximal

portion 130 of the **catheter** 100 is a handle chassis 160 for housing necessary steering and positioning controls, as will be described in further details below.

Incorporated at a proximal end 160 of the **catheter** 100 is a coupling 170 for connecting the **catheter** 100 to one or more electronic devices such as a RF generator and controller (not shown) in support of the ablation **procedure**.

[47] The dimensions of **catheter** 100 are adapted as required to suit the particular medical **procedure**, which are well known in the medical art. In a preferred embodiment, the **catheter** 100 is used to ablate cardiac tissue; however, the **catheter** 100 may be used to **ablate** other types of body tissue.

The tubular body 120 of the **catheter** may be generally constructed of a polymer material that is bio-compatible within the body...

...polyurethane, polyester, polyimide and polyamide, with varying degrees of radiopacity, hardness and elasticity.

[48] The **catheter** 100 may be formed with a plurality of segments using one or more of the aforementioned materials such that the **catheter** body 120 is progressively more flexible toward its distal end. The segments may be joined...

...tubular body 120 to attain the desirable level of stiffness and torsional strength for the **catheter** 100. This allows the **catheter** 100 to advance and negotiate through the body vessel of a patient, and to enable torque transfer along the length of the **catheter** from the proximal portion to the distal portion.

[49] With reference additionally to FIGS. 3A, B, the distal portion 140 of **catheter** body 120 may include a softer polymer compound than the proximal portion 130, with little...

...to provide the desired flexibility to

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accommodate distal deflection and shaping of the shapeable **antenna** apparatus 110. Deflection and shaping of the shapeable **antenna** apparatus

110 may be implemented through the use of a pre-shaped deflection member **catheter** body 140.

[50] The pre-shaped deflection member 180 and/or the deflection regulating member...

...200 along the axial slot, together enables a physician to shape or deflect the shapeable **antenna** apparatus 110 between a straight configuration (FIG. 1A) and a deflected, shaped configuration...pressure switch or self-locking mechanisms.

[51] FIGS. 2A and 2B illustrate a RF ablation **catheter** 210 similar to the RF ablation **catheter** 100 described above, but with an alternative embodiment of a deflection control mechanism 220 for shaping or deflecting the shapeable **antenna** apparatus 110. The deflection control mechanism 220 may include

a rotatable collar 230...relative to the handle shaft 240 enables a physician to shape or deflect the shapeable

**antenna** apparatus 110 between a straight configuration (FIG. 2A) and

a

10

deflected, shaped...configuration  
therebetween.

[52] With reference to FIGS. 3A and 313, an embodiment of the shapeable **antenna** apparatus 110 will now be described in more detail. The distal

portion of the **catheter** body 140 includes a RF **antenna** 250 having a flexible, helically coiled RF radiating **antenna** element 255 for body tissue ablation. In a representative embodiment, the RF **antenna** 250 includes an electrically conductive material or wire strip that is wound in a helical...wire strip are a matter of design choice, which can vary according to the particular **procedure** and flexibility requirements.

[53] The RF **antenna** 250 is adapted to receive and radiate electromagnetic energy from a source of radio-frequency...

...radio frequency is that of the microwave frequency range typically above 300 MHz. The RF **antenna** 250 is capable of applying substantially uniformly distributed electromagnetic field energy along the RF **antenna** 250, which is independent of the contact between the RF **antenna** 250 and the tissue to ...ablated. The electromagnetic field transmitted is substantially normal to the longitudinal axis of the RF **antenna** 250, and therefore producing a uniform energy field circularly about and bounded by the RF **antenna** 250.

[54] The RF **antenna** 250 may be in electrical contact with one or more electrical conductors 260, which extends proximally from the RF **antenna** 250 to the handle chassis 160. As described in detail below with respect to FIGS...

...630. An inner surface of the sleeve 630 defines the lumen 150.

[55] The RF **antenna** 250 and the one or more electrical conductors 260 may be coated with a polymeric...electrical components, and to help confine the electro-magnetic field to outside of the shapeable **antenna** apparatus 110. The encapsulant, coating, or layer may be made of suitable materials...regulating member 190 to conform the shapeable antenna apparatus 110 to the desired **linear** or **curvilinear** profile, thus, facilitating optimal configuration and placement of the shapeable **antenna** apparatus 110 along the internal contour or geometry of the targeted site.

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[58] In the embodiment of the shapeable **antenna** apparatus 110 illustrated

in FIGS. 3A, 313, the shape of the shapeable **antenna** apparatus 110 is prescribed by the **pre-shaped** deflection member 180 by sliding the pre shaped deflection member 180 distally out of the...

...member 190 (via the deflection control mechanism at the handle chassis 160) and into the **lumen** 150.

[59] Proper shaping and placement of the shapeable **antenna** apparatus 110 may be aided by one or more radio-opaque markers (not shown) carried

by the shapeable **antenna** apparatus 110. With one or more radio-opaque 110 marks, the shapeable **antenna** apparatus 110 becomes opaque under

x-ray or fluoroscopic examination, thereby aiding the identification of its position during shaping and placement of the shapeable **antenna** apparatus II 0 for tissue ablation.

[60] In addition, the shapeable **antenna** apparatus 1 1 0 may carry one or more intracardiac electrocardiogram ("ECG") electrodes (not shown their actions. These electrodes may be secured along the length of the shapeable **antenna** apparatus 1 1 0.

[61] With reference to FIG. 4A an alternative embodiment of a shapeable **antenna** apparatus 280 is shown where, similar to FIG. 4A, the shape of the shapeable **antenna** apparatus 280 is prescribed by the **pre - shaped** deflection member 180. However, in this embodiment, the pre-shaped deflection member 180 shapes the shapeable **antenna** apparatus 280 to a desired configuration by slidably retracting the deflection regulating member 190 proximally shape, which, in turn, causes the shapeable **antenna** apparatus 280 to take the desired configuration.

[62] FIGS. 5A, 5B and FIGS. 6A, 6B illustrate further respective embodiments of a shapeable **antenna** apparatus 290, 300 in a straight configuration and a shaped configuration. In FIGS. 5A, 5B, the shapeable

**antenna** apparatus 290 is similar to the shapeable **antenna** apparatus 1 1 0 described above with respect to FIGS. 3A, 3B in that the shapeable **antenna** apparatus 290 takes a desired configuration by sliding a distal portion 310 of a pre deflection regulating member 330. In FIGS. 6A, 6B, the shapeable **antenna** apparatus 300 is similar to the shapeable **antenna** apparatus 280 described above with respect to FIGS. 4A, 4B in that the shapeable **antenna** apparatus 300 takes a desired configuration by sliding a deflection regulating member 340 axially away...

...340 and pre-shaped deflection member 320, 360 that may be used with the shapeable **antenna** apparatus 290, ...360 in a straight configuration (or other desired configuration) prior to shaping of the shapeable **antenna** apparatus 290, 300.

[65] In FIG. 713, the deflection regulating member 330, 340 has a...the deflection regulating member 330, 340.

[67] With reference to FIG. 8, a RF ablation **catheter** 400 including a shapeable **antenna** apparatus 41 0 constructed in accordance with another embodiment of the invention will be described. The RF ablation **catheter** 400 is similar to the **catheter** 1 00 described above with respect to FIGS. 1A, 1 B

and 2A, 213, except the shape of the shapeable **antenna** apparatus 410 is

regulated by a hydraulic or pneumatic fluid pressure instead of the deflection I 0 regulating member 190. At a proximal end of the **catheter** 400, a stop cock 420 may be used to connect the **catheter** 400 to a hydraulic or pneumatic fluid pressure source 430. In the embodiment shown, the...with respect to FIGS. 4A, 4B may be fully deployed or integrated into the shapeable **antenna** apparatus 41 0 so that the **antenna** apparatus 41 0 takes the shape of the **pre - shaped** deflection member 180 as shown in FIG. 9A.

The pre-shaped deflection member 180 may be disposed in the one or more lumens 150 of the catheter 400, may be disposed in the antenna 250, may be disposed in the wall of the catheter body 120, or the catheter body 120 may be pre-shaped. To straighten the shapeable antenna apparatus 410 to the configuration shown in FIG. 913, fluid pressure may be imparted to the interior of the distal portion 140 of the catheter 400 by the fluid pressure source 430. For example, with a valve of the stop...

...causing fluid from the syringe to be injected into the distal portion 140 of the catheter body 120. This causes pressure to be exerted in the shapeable antenna apparatus 410 generally in the direction of the pressure arrows shown, straightening the pre-shaped shapeable antenna apparatus 410. The shapeable antenna apparatus 410 may be maintained in the straight configuration shown in FIG. 9B by closing the valve on the stop cock 420 so that fluid in the catheter body 120 does not escape the catheter body 120.

To return the shapeable antenna apparatus 410 to the configuration shown in FIG. 9A, the valve on the stop cock...

...430 may be withdrawn. This removes the fluid from the distal portion 140 of the catheter body 120, and the shapeable antenna apparatus ...the shape of the pre-shaped deflection member. Thus, the fluid pressure in the shapeable antenna apparatus 410 serves the same function as the deflection regulating member described above, and the control of fluid pressure to the shapeable antenna apparatus (e.g., through the syringe fluid pressure source 430 and the stop cock 420...

...69] In another embodiment, where the pre-shaped deflection member 180 is disposed in the antenna 250, is disposed in the wall of the catheter body 120, or the catheter body 120 is pre-shaped, a ...be slidably received within the elongated lumen 150 for regulating the deflection of the shapeable antenna apparatus.

[70] The shapeable antenna apparatus will now be generally described in use. The catheter is inserted through an opening into a body vessel of a patient where it is brought into the proximity of target tissue for ablation.

Prior to the insertion, the shapeable antenna apparatus is provided in the straight configuration. Once inserted, the distal portion 140 of the catheter is manipulated to reach within the proximity of the location where ablation is needed. Steering of the catheter through the patient's vasculature to the target ablation site may be done using a steering assembly of the catheter and/or, steering of the distal portion 140 of the catheter to the target ablation site may be performed using the shapeable antenna apparatus and the.

deflection control mechanism described above. Directional control may be accomplished with the...

...200, the rotatable collar 230, or by

1 6

controlling fluid pressure to the shapeable **antenna** apparatus (e.g., with **catheter** 400).

[71] Placement, shaping, and deflection of the shapeable **antenna** apparatus may be ...by one or more radio-opaque markers placed on the distal portion 140 of the **catheter**. The position of the one or more radioopaque markers may be detected by suitable x...

...or fluoroscopic means, as practiced in the art. After the distal portion 140 of the **catheter** is placed

within the proximity of the tissue ablation site, the shapeable **antenna** apparatus may be shaped to a desired configuration by any of the **processes**

0 described above for shaping the shapeable **antenna** apparatus (e.g., deploying the **pre - shaped** deflection member distal of the deflection regulating member so that the shapeable **antenna** apparatus takes the shape of the distal portion of the **pre - shaped** deflection member, retracting the deflection regulating member in a direction proximal of the distal portion of 5 the pre-shaped deflection member so that the shapeable **antenna** apparatus takes the shape of the distal portion of the **pre - shaped** deflection member, releasing fluid pressure from the distal portion 140 of the **catheter** so that the shapeable **antenna** apparatus takes the shape of the distal portion of the pre shaped deflection member). The shapeable **antenna** apparatus is manipulated to the desired shaped for optimal ablation of target body tissue.

Alignment of ,the RF **antenna** 250 with the target ablation site may be further aided with the use of the...

...example, in the case of an atrium of the heart, the shape of the shapeable **antenna** apparatus may be adjusted to conform to the contour of the interior wall of the atrium to allow at least a portion of the shapeable **antenna** apparatus to rest upon the atrial wall, which establishes **line** contact

between the atrium and the shapeable **antenna** apparatus. The shapeable **antenna** apparatus is flexible enough to allow at least a portion of the

shapeable **antenna** apparatus to conform to the internal contour of body vessel and to rest against its internal wall. As the atrial wall pulsates, the shapeable **antenna** apparatus, which is in contact with the atrial wall, will also

1 7

move in...

...body vessel where treatment is desired.

[73] Once the desired shape profile for the shapeable **antenna** apparatus has been acquired and aligned in parallel with the desired ablation pathway,

the shape of the shapeable **antenna** apparatus may be secured ... ablation can be accomplished with the application of radio-frequency energy.

Depending on the particular **procedure** requirements, the length of the

I 0 ablation can be adjusted by positioning the RF **antenna** along various target tissue locations followed by applications of the RF energy. Thus, long and contiguous ablation **lines** can be easily established to substantially eliminate the risk of electrical impulse leakage between **ablated** tissue pathways.

[74] The above may be repeated or performed for other locations within 1 5 the **atrium** or other regions of the body as necessary depending on the particular **procedure** requirements.

[75] From the above description, it is apparent that the shapeable **antenna** apparatus of the present invention allows the electrodes to quickly, easily, and precisely achieve optimum...

...being applied to the target tissue to bring about therapeutic effects.

[76] WithreferencetoFIGS 11C, anotherembodimentofaradiofrequency **catheter** 500 for **ablating** biological tissues of a body vessel, such as, but not limited to the **atrium** of a patient, will be described. The **catheter** 500 is adaptable for insertion into a body vessel and includes a deflectable

**catheter** guide 510 that is located within a **catheter** lumen 520. The deflectable **catheter** guide 510 may be located in the **catheter** 500 in addition

to the shapeable **antenna** apparatus described above. Alternatively, the **catheter** 500 may include the deflectable **catheter** guide 510, but not the

shapeable **antenna** apparatus. A radio-frequency or microwave **antenna** 530

is provided at a distal portion 540 of the **catheter** 500. The **antenna** 530

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receives and transmits radio-frequency (microwave) energy for tissue ablation.

[77] The **catheter** guide 510 prescribes the ablation pathway of the **antenna** 530 for tissue ablation. In a representative embodiment of the invention, the **catheter** guide 510 includes elongated portions that are secured to a slide control mechanism 560 of a **catheter** handle 570 outside the body vessel for deflection, steering, positioning and deployment control.

[78] A connection cable 580 extends from a proximal end 590 of the **catheter** handle 570 and includes an electrical connector or coupling 600 for

connecting the **catheter** 500 to one or more integrated and/or separate electronic devices such as, but not limited to, a RIF generator, an ECG **system**, and controller (not shown) in support of the ablation **procedure**.

[79] A **catheter** positional control 610 may extend from the proximal end 590 of the **catheter** handle 570 for steering the **catheter** 500 through the 5 patient's vasculature and/or for controlling axial movement of the **catheter** guide 510.

[80] The RIF **antenna** 530 may include an electrically conductive material or wire strip that is wound 'in a...wire strip are a matter of design choice, which can vary according to the particular **procedure** and

flexibility requirements.

[81] To enhance its shape integrity, the RIF **antenna** 530 is provided with an inner **tubing**, tubular liner, or sleeve 630, which has a flexible extended body extending from the helical coil 620 proximally toward the handle 570 of the **catheter** 500. Sleeve 630 is constructed of a dielectric material, which reduces the likelihood of electrical short between the metallic surfaces of helical coil 620 and body fluids in the **lumen** 520, and to help confine the electromagnetic field to the outside of the **lumen** 520.

[82] The helical coil 620 is electrically coupled to a first or inner conductor...and thermal isolation from the biological environment.

[88] Thus, the distal portion 540 of the **catheter** 500 includes a set of electrical conductors, each of which is formed in an elongated conductors 640, 660 (which may be helically coiled) and the helically coiled **antenna** 530 maximize the electrically conductive surface area, and, hence, efficiency of the microwave energy delivery, while providing a central coaxial **lumen** to accommodate the **catheter** guide and/or shapeable **antenna** apparatus.

Although the **lumen** 520 is shown coaxial with the conductors 640, 660, in an alternative embodiment, the **lumen** 520 may include one or more **lumens**, one or more of which may not be coaxial with the conductors 640, 660.

[89] The **catheter** guide 510 may be longitudinally deployed from the 10 **catheter** 500 within ...vessel and is flexibly conformable to the contour of the body vessel. Alignment of the **catheter** guide 510 with the desired tissue ablation pathway may be facilitated with the use of one or more radio opaque markers and intracardiac electrodes mounted along the **catheter** guide 510. In an alternative embodiment, the **catheter** guide 500 may be 15 fixed relative to the **catheter** 500.

[90] The **catheter** guide 510 includes an elongated flexible spine 680 with a distal end portion 690 including distal portion of the **antenna** 530, at the distal end of the **catheter** 500, so that the atraumatic tip 700 is adjacent to the **antenna** 530. In an alternative embodiment, the **catheter** guide 510 may be fixed to the **catheter** 500 so that the atraumatic tip 700 extends a distance from the end of the **catheter** 500.

[91] The tip 700 is atraumatic to reduce the potential for perforating a body...

...700 is formed of radio-opaque material to support identification of the location of the **antenna** 530 during administration of the ablation procedure.

[92] ...made of such SMA material. The use of SIVIA material enables pre-shaping of the **catheter** guide 510 or distal portion 540 of the **catheter** 500 to conform the **catheter** body to attain a desired **curvilinear** profile, thus facilitating the navigation and placement of the **catheter** 500 to the internal contour or geometry of the body vessel. Means and **methods** for pre-shaping of SIVIA materials are generally known in the art and are not discussed in details here.



[95] Examples of pre-shaped configurations of the **catheter** guide ...or curve.

[96] With reference to FIGS. 12A-1 9, an another embodiment of a **catheter** guide 71 0 will be described. The **catheter** guide 71 0 includes a spine 680, an atraumatic tip 700, and a second elongated strip or pull wire tendon 720 that extends within the **catheter** lumen 520 along the length of the spine 680.

The ...longitudinal slot 770 enables a physician to deflect the distal end portion 690 of the **catheter** guide. A frictional capture mechanism (not shown) may be incorporated in the thumb slide 740...junction 800 through the connection cable 580 for transmitting ECG signals between an external ECG **system** and the one or more ECG electrodes at the distal- portion 540 of the **catheter** 500. One or more 1 5 additional conductors may extend through the connection cable 580 for connecting electrical aspect of the **catheter** 500 to one or more external electrical systems. The connection cable 580 includes an insulating jacket 830 and terminates at electrical coupling 600 for coupling the **catheter** 500 to one or more external electrical systems.

[98] With reference specifically to FIGS. 12A...portion 840.

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[99] FIGS. 13 and 14 illustrate the distal portion 540 of the **catheter** 500 in a straight configuration and a deflected configuration, respectively. In the straight configuration shown...

...pull on the atraumatic tip 700. In the deflected configuration shown in FIG.

14, the **catheter** guide 71 0 is deflected or bent by the pull wire tendon 720 pulling on...a bi-metal or shape-memory alloy ("SMA") material to enable pre-shaping of the **catheter** guide 71 0 or 0 distal portion 540 of the **catheter** 500 to conform the **catheter** body to attain a desired **linear** profile. Examples of pre-shaped configurations of the **catheter** guide 710 in application are shown in FIGS. 18A and 18B. In FIG. 18A, the the slide control mechanism 750 may cause the **catheter** guide 71 0 and distal end portion 690 of the **catheter** 500 to assume a pre-shaped configuration or a straight configuration.

[101] With reference to FIGS. 15 and 16, an alternative embodiment of a **catheter** guide 845 is shown. In this embodiment, the **catheter** guide 845 includes an elongated tubular body 850 that surrounds and houses the spine 680...the pull wire tendon 720 are exposed. The elongated tubular body 850 includes a tubular **lumen** 870 that the spine 680 and the pull wire tendon 740 extend through.

[102] In FIG. 16, a distal portion of the **catheter** guide 845 extends distally beyond an end of the **catheter** body to define a guide leader 880 . The length L of the guide leader 880...

...on the particular

application as defined by the relative location or distance between the RF **antenna** 530 and the atraumatic tip 700. The atraumatic tip 700 serves as an anchor for the **catheter** 500. The length L of the guide leader 880 can be

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predetermined and fixed during the manufacture of the **catheter** 500.

Alternatively, the length L of the guide leader 880 may be adjustable and once **catheter** 500 (and helical **antenna** 530) to the body vessel with 0 reduced risks of puncture. The flexibility of the **catheter** guide 845 enables it to flex to conform to the contour of the body vessel thereby securing the

ablation pathway for the radio-frequency or microwave **antenna** 530. With the deflectable **catheter** guide 845 disposed within the **lumen** 520, the distal portion 540 of the **catheter** 500 conforms to the **linear** profile of the **catheter** 5 guide 845. The pull wire tendon 720 attached to the atraumatic tip 700 of the **catheter** guide 845 provides further steering capability to the **catheter** guide 845. Manipulation of the spine 680 and the pull wire tendon 720 individually or...

...proximally) at the slide control mechanism 750 provides further changes in the shape of the **catheter** guide 845 (and therefore the distal portion 540 of the **catheter** 500) and in directional steering. Thus, in addition to providing pre-shaping to the deflectable **catheter** guide 845 (and, therefore, the distal portion 540 of the **catheter** 500), the **catheter** 100 offers substantial capabilities and versatility within the body vessel.

[104] Optionally, one or more intracardiac electrocardiogram ("ECG") electrodes may be mounted on or within the **catheter** guide 845 to support collection of intracardiac electrical signals when the **catheter** 100 is deployed.

[105] With reference to FIGS. 20A-20C, an embodiment of a **catheter** guide 900 with bidirectional deflection control will now be described. The **catheter** guide 900 is similar to the **catheter** guide 710 described above, but the

**catheter** guide 900 includes a pair of opposite pull wire tendons 930, 940 extending along the length of the **catheter** guide 900 to provide bidirectional

25

deflection or steering of a spine 915 within a **lumen** 950. The pull wire tendons 930, 940 ...for controlling movement of the pull wire tendons 930, 940, and, hence, deflection of the **catheter** guide 900.

[106] In use, actuation of the slide control mechanism may cause one of the pull wire tendons 930 to pull on the atraumatic tip 970...pull on the atraumatic tip 970 in the opposite direction.

Bidirectional deflection control of the **catheter** guide 900 gives the physician more control of the configuration of the distal portion of the **catheter**.

Although unidirectional deflection control and bidirectional deflection control

have been described, the **catheter** guide 900 may be configured for deflection control in other numbers of directions (e.g...

...effectively reduces, if not avoids, the need for repetitive pinpoint precision placement of an ablation **catheter antenna** (as was performed in the prior art), but also provides substantial navigational capabilities for deployment of the **antenna 530** within the body vessel. The present invention conveniently places the radio-frequency **antenna 530** along the locus of a **catheter** guide that defines the tissue ablation pathway. At the same time, the present invention ensures...

...in the prior art). Accordingly, the present invention substantially accomplishes the objective of the Maze **procedure** in achieving **curvilinear lesions** without the need for open-heart surgery. These and other aspects and advantages of the...

#### Claim

1 . A shapeable **curvilinear** radio-frequency **antenna** apparatus for ablating biological tissue within the body vessel of a patient, comprising:  
a) a flexible **catheter** body including a distal portion and an elongated **lumen** ;  
b) inner and outer coaxially aligned conductors extending within the **catheter** and coaxial with the **lumen** ; and  
c) a flexible shapeable **curvilinear** radio-frequency **antenna** carried by the distal portion of the flexible **catheter** body and in electrical communication with the inner and outer coaxially aligned conductors, the flexible shapeable **curvilinear** radio-frequency **antenna** adaptable to receive and transmit radio-frequency energy for ablating biological tissue and shapeable between a straight configuration and a **curvilinear** configuration for creating a **curvilinear** ablation pattern in biological tissue within the body vessel of a patient.

2 The antenna...

...further including a pre-shaped deflection member carried by the flexible shapeable **curvilinear** radio-frequency **antenna** adaptable to take a **pre - shaped** memory configuration, and a deflection regulating member operatively associated with the pre-shaped deflection member changing the configuration of the flexible shapeable **curvilinear** radio-frequency antenna between a straight configuration and a pre-shaped memory **curvilinear** configuration. 1

3 The **antenna** apparatus of claim 2, wherein the **pre - shaped** deflection member is an elongated, flexible spine made of a shape-memory alloy and longitudinally disposed in the elongated **lumen** .

4 The **antenna** apparatus of claims 1 or 2, wherein the deflection regulating member is an elongated, rigid member longitudinally adjacent to the preshaped deflection member in the elongated **lumen** .

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. The **antenna** apparatus of any of claims 2-4, wherein at least one of the

...the flexible **curvilinear** radio

frequency antenna between a straight configuration and a pre-shaped memory **curvilinear** configuration.

6 The **antenna** apparatus of claim 2, further including a fluid pressure source and the deflection regulating member is fluid pressure within the elongated

**lumen** from the fluid pressure source.

7 The **antenna** apparatus of any of claims 1-6, further including a deflectable **catheter** guide disposed within the elongated **lumen** and terminating distally of a distal end of the **catheter** to define a biological ablation pathway.

8 The **antenna** apparatus of claim 7, wherein the distal portion of the deflectable **catheter** guide includes an atraumatic tip.

9 The **antenna** apparatus of claims 7 or 8, wherein the deflectable **catheter** guide extends distally from the distal opening to define a guide leader.

10. The **antenna** apparatus of claim 9, wherein the guide leader has a manually adjustable length.

11. The **antenna** apparatus of claim 9, wherein the guide leader has a predetermined fixed length.

12 The **antenna** apparatus of any of claims 7-11, wherein the deflectable

**catheter** guide has variable stiffness along at least part of its length. 13. The **antenna** apparatus of any of claims 7-12, wherein the deflectable

**catheter** guide further comprises a pull wire tendon slidably disposed within the **catheter lumen** for deflecting the **catheter** guide.

14 The **antenna** apparatus of any of claims 1-13, wherein the radio-frequency

**antenna** is adaptable to receive and transmit microwave energy at a frequency greater than 300 Megahertz. 15. A **method** of ablating biological tissue within the body vessel of a patient, comprising the steps of:

a) providing a shapeable **curvilinear** radio-frequency **antenna** apparatus for ablating biological tissue within the body vessel of a patient, the shapeable **curvilinear** radio-frequency **antenna**

apparatus including a flexible **catheter** body including a distal portion and an elongated **lumen**, inner and outer coaxially aligned conductors extending within the **catheter** and coaxial with the **lumen**; and a flexible shapeable **curvilinear** radio-frequency **antenna** carried by the distal portion of the flexible **catheter** body and in electrical communication with the inner and outer coaxially aligned conductors, the flexible shapeable **curvilinear** radio-frequency **antenna** adaptable to receive and transmit radio-frequency energy for ablating biological tissue and shapeable between a straight configuration and a

**curvilinear** configuration for creating a **curvilinear** ablation pattern in

biological tissue within the body vessel of a patient;

b) delivering the shapeable **curvilinear** radio-frequency **antenna** apparatus to a targeted body tissue ablation site within the body vessel of a patient...

...configuration to a pre-shaped memory

**curvilinear** configuration so that the flexible **curvilinear** radio

frequency **antenna** is adjacent to the body tissue to be ablated; and  
d) ablating the body tissue using the flexible shapeable **curvilinear**  
radio-...member  
carried by the flexible curvilinear radio-frequency antenna adaptable to  
take  
a pre-shaped **curvilinear** memory configuration, a deflection regulating  
member operatively associated with the pre-shaped deflection member for

...the deflection of said pre-shaped deflection member, and  
changing the configuration of the flexible **curvilinear** radio-frequency  
**antenna** includes controlling at least one of the **pre - shaped**  
deflection  
member and the deflection regulating member to change the configuration  
of the flexible curvilinear...to a pre-shaped memory curvilinear  
configuration so that the  
30  
flexible curvilinear radio-frequency **antenna** is adjacent to the body  
tissue to  
be ablated.

17 The **method** of claim 16, wherein the pre-shaped deflection member is  
an  
elongated, flexible spine made of a shape-memory alloy and  
longitudinally disposed in the elongated **lumen**.

18 The **method** of claims 16 or 17, wherein the deflection regulating  
member  
is an elongated, rigid member longitudinally adjacent to the pre-shaped  
deflection member in the elongated **lumen**.

19 The **method** of any of claims 16-18, wherein controlling ...shaped  
deflection member and the  
deflection regulating member for changing the configuration of the  
flexible **curvilinear** radio-frequency **antenna** from a straight  
configuration to a **preshaped** memory configuration. 15 20. The **method**  
of claims 16 or 17, further including a fluid pressure source and  
the deflection regulating member is fluid pressure within the elongated  
**lumen** from the fluid pressure source, and controlling at least one of  
the pre  
shaped deflection member and the deflection regulating member includes  
supplying the elongated **lumen** with fluid pressure from the fluid  
pressure source to change the configuration of the flexible **curvilinear**  
radio-frequency  
**antenna** from a straight configuration to a **pre - shaped** memory  
configuration.

21 The **method** of any of claims 16-20, wherein the shapeable  
**curvilinear**  
radio-frequency **antenna** apparatus includes a deflectable **catheter**  
guide  
disposed within the elongated **lumen**, the **catheter** guide including a  
distal  
end; and the **method** further including positioning the radio-frequency  
**antenna** of the **catheter** adjacent to the body tissue to be ablated by  
anchoring the distal end of the **catheter** guide in the body vessel and  
Cideflecting the **catheter** guide so that the radio-frequency **antenna**  
of the  
**catheter** is adjacent to the body tissue to be ablated.

22 The **method** of claim 21, wherein the distal portion of the  
deflectable

**catheter** guide includes an atraumatic tip, and anchoring the distal end of  
31  
the **catheter** guide in the body vessel includes anchoring the atraumatic tip  
of the **catheter** guide in the body vessel.

23 The **method** of claims 21 or 22, wherein the deflectable **catheter** guide extends distally from an end of the **catheter** body to define a guide leader, and deflecting the **catheter** guide includes deflecting at least the guide leader.

24 The **method** of any of claims 21-23, wherein the deflectable **catheter** guide further comprises a pull wire tendon slidably disposed within the elongated **lumen**, and deflecting the **catheter** guide includes using the pull  
I 0 wire tendon to cause the **catheter** guide to deflect.

25 The **method** of any of claims 21-24, wherein the guide leader has a manually adjustable length, and the **method** further includes manually adjusting the length of the guide leader before deflecting the **catheter** guide. 1 5 26. The **method** of any ...of claims 21-24, wherein the guide leader has a predetermined fixed length.

27 The **method** of any of claims 15-26, wherein the radio-frequency **antenna** is adaptable to receive and transmit microwave energy at a frequency greater than 300 Megahertz...

22/3,K/28 (Item 28 from file: 349)  
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Good!!!

00996886 \*\*Image available\*\*

**METHODS AND APPARATUS EMPLOYING IONIZING RADIATION FOR TREATMENT OF CARDIAC ARRHYTHMIA**

**METHODES ET DISPOSITIF UTILISANT UN RAYONNEMENT IONISANT POUR LE TRAITEMENT DE L'ARYTHMIE CARDIAQUE**

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Detailed Description

Claims

Claims  
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Detailed Description

... is referred to as ablation. After the source of the disruption in the electrical system is determined, the tissue of the heart is ablated to eliminate the source of the aberrant impulses or to form a lesion or scar which interrupts and isolates the source of the aberrant electrical signal. It has been proposed...

...shapes of cryogenic probes that may be used to carry out the so-called MAZE procedure in which a series of lesions are formed strategically around the pulmonary trunk and elsewhere in the heart muscle to create an electrical maze that delays the aberrant electrical signals and prevents fibrillation of the atrium. ...entirety.

Although cryosurgical probes and rf energy electrodes are used with increasing frequency in treating **cardiac arrhythmias** via heart tissue **ablation**, there continues to be a desire for additional apparatus and methods in the armamentarium of **cardiologist** for the detection and treatment of cardiac **arrhythmia**. For example, forming continuous **linear lesions** without breaks or disruptions and of uniform depth along the entire **lesion** lengths are challenging at the very least for cardiologists and electrophysiologists. Additionally, determination of the known as electrophysiology mapping -which is commonly carried out as a separate **procedure**.

It would be advantageous if the mapping and ablation could be carried out with the same instrument in the same **procedure**.

There also continues to be a desire for additional apparatus and **methods** in the armamentarium of cardiologist for the treatment or prevention of conditions resulting from the treatment of cardiac **arrhythmias**. For example, it is known that **ablation** around the pulmonary vein will sometimes result in stenosis, or closure, of the vein. Despite...the pulmonary vein often have a doubtful prognosis. Accordingly, there is a need to provide **method** and apparatus for alleviating stenosis of the pulmonary and other veins, that may be caused by other **ablation** treatment of **cardiac arrhythmias**.

#### SUMMARY OF THE INVENTION

The present invention is directed, in one aspect, to **methods** and apparatus which employ ionizing radiation for ablating heart tissue to treat cardiac arrhythmias, including without limitation both impulse conduction and impulse generation **arrhythmias**, and both **ventricular** and **atrial arrhythmias**. In accordance with this aspect of the ...undue experimentation) is sufficient to ablate the tissue and obtain the desired treatment of the **arrhythmia**.

This **method** may be achieved by a radioactive tipped **catheter** or wire or, more preferably, by employing a **catheter** such as the Beta-Cath' **catheter** (presently sold ...which a train of radioactive sources are hydraulically advanced into the distal end of the **catheter** after it is properly positioned against the wall of the heart where the ablation...

...train may be of any desired length, which may be varied, to create the desired **linear lesions** in the heart muscle. Such a **catheter** lends itself particularly well to endocardial placement through the vascular **system** of the patient, and to the MAZE type **procedure** in particular. However, the present invention is not limited to an endocardial approach and ...s) epicardially, on the outside surface of the heart, either by an open chest **procedure** or by a minimally invasive **procedure** through a trocar, endoscope or the like.



In accordance with a more specific aspect of the present invention, and particularly for endocardial applications, the delivery **catheter** may have means on the distal end to allow for steering and/or for active arrangement or a loop located on the distal end of the

**catheter** that may be deployed from a retracted position during **catheter** placement to a deployed position in which the basket or nest or loop rests against an opposing surface of the heart chamber to hold the **catheter** at the desired location for the ablation. In other words, upon deployment, the basket or nest or loop would engage against an opposing wall surface and hold or push the **catheter** against the inside surface of the wall or in close proximity to it at the...allows deployment of the basket or nest or loop.

Alternatively, the distal end of the **catheter** may be preformed into a desired shape, such as a classic pigtail shape or a...

...or lasso. For example, a predetermined shape may be formed on the end of the **catheter** by thermally presetting or by other known **techniques**. Alternatively, or additionally, a **guide wire** could be used to assist in retaining the distal end of the **catheter** in the desired shape or to form an otherwise straight and flexible **catheter** into the desired shape.

Any of the above embodiments of the preferred **catheter** has the advantage of allowing the **catheter** to be accurately placed within the heart, and inside the atrium and the pulmonary veins in particular, before the radioactive sources are introduced into the **catheter** thus minimizing unnecessary radiation exposure; to create **linear lines** of ablation at the desired locations of selected and variable length; to permit repositioning of the **catheter** while the radioactive sources are outside the patient's body when treating multiple sites; and to reduce the treatment time as compared to other **procedures** and avoid the need to perform the highly invasive open chest MAZE surgical **procedure**.

In accordance with a further aspect of the present invention, ionizing radiation may be employed...

...modify, without complete ablation, the conduction characteristics of the AV node to treat or prevent **arrhythmias** arising from AV node malfunction. Prior **procedures** have typically required complete ablation of the AV node to treat certain **arrhythmias**. one drawback with this approach is that it requires permanent implantation of a pacemaker to replace the function of the AV node.

Apparatus and **methods** which permit modification of the conduction characteristics of the AV node without complete ablation would be a particular advance over prior **methods** and apparatus for treating **arrhythmias** related to AV node malfunction, such as re-entrant

**tachycardias .**

In connection with a further aspect of the present invention a **catheter** embodying the features of the present invention may be used in combination with an instrument...heart of Figure 1.

Figure 3 is a diagrammatical view of a radioactive source delivery **system** that may be employed in the present invention.

Figure 4 is a generally diagrammatical plan...

...for a radioactive source for attachment to the proximal end of a radioactive source delivery **catheter** .

Figure 5a is a cross-sectional view of the distal end of a radioactive source delivery **catheter** that may be employed in the present invention.

Figure 5b is a cross-sectional view of the **catheter** of Figure 5 a, taken along line Sb-5b.

Figure 6 is a perspective view of the radiation source delivery device and **system** that may be coupled to a radioactive source delivery **catheter** of the type shown 1S in Figures 5a and 5b.

Figure 7a is a cross-sectional view of the right atrium of the human heart, showing a **guide wire** having a **preformed** distal end shape inserted into the right atrium through an introducing **catheter** or sheath placed in or at the Inferior Vena Cava.

Figure 7b is a cross-sectional view of the human heart, showing a **guide wire** having a **preformed** distal end pig-tail or spiral shape inserted into the pulmonary vein through an introducing **catheter** or sheath placed in or at the Inferior Vena Cava.

Figure 8 depicts **method** and apparatus of the present invention in which a **catheter** is inserted into the right atrium along the pre-formed **guide wire** , and after a radioactive source train has been introduced into the **catheter** and advanced to the distal end, where they lie in close proximity to or directly...

...9a is a cross-sectional view of the distal end of another embodiment of a **catheter** embodying the present invention, ...wires that may be used to adjust the shape of the distal end of the **catheter** .

Figure 9b illustrates the distal end of the **catheter** of Figure 9a formed into a **curvilinear** shape to lie against the atrial wall.

Figure 10a is an elevational view of the distal end of another **catheter** embodiment that may be employed in connection with the present invention, employing a basket

arrangement...

...position

during entry into the heart to an expanded or deployed position to urge the **catheter** against the heart wall at the location to be ablated.

Figure 10b is a longitudinal cross-sectional view of the **catheter** of Figure 10a taken along line 10b-10b.

Figure 10c is an elevational view of the **catheter** of Figure 10a showing the basket in an expanded or deployed position.

Figure 11a is a cross-sectional view of the distal end of another **catheter** embodiment that may be used in the present invention, employing a self-expanding basket or nest to hold the **catheter** in the desired position for ablation.

Figure 11b is an elevational view of the **catheter** of Figure 11a with a sheath introducer overlying and compressing the basket.

Figure 11c is an elevational view of the **catheter** of Figure 11b with the sheath pulled back (or the **catheter** advanced) and the basket expanded to brace the **catheter** against the wall of the heart at the desired location for ablation.

Figure 12 is a cross-sectional view of the human heart, showing a **guide wire / catheter** having a **preformed** distal end shape to engage the atrial wall around the ostium of one or more...

...pulmonary vein(s) from the remainder of the atrial wall.

Figure 13a-c showing a **catheter** embodying the ...steering wire further actuating device.

Figure 14 is a perspective cross-sectional view of a **catheter** embodying another inventive aspect relating to steering wire control, and illustrating a steering wire curve...

...segment and a steering wire bend.

Figure 15 is a perspective cross-sectional view of **catheter** embodying a **lumen** connector in the distal end of the **catheter** for connecting a radiation source **lumen** and fluid return **lumen**.

Figure 16 is a cross-sectional view of a **catheter** to reduce steering wire interference with radiation ablation.

#### MORE DETAILED DESCRIPTION

Figure 1 ...sequential contraction of various chambers of the heart is controlled by the heart's electrical **system**. Referring to Figure 2, each

normal heartbeat begins with the generation of an electrical signal...19 (or abnormal pathways recognized in the WWP syndrome for example, which are treated by " **ablation** " also). Eventually the fibers of the Bundle of His branch out even further into the **ventricle** muscle, where they are called Purkinje fibers 21. This **system** of conduction rapidly transmits the electrical signal to the particular ventricular muscles, causing contraction of...

...of the body. It should therefore be apparent how vital it is that the electrical **system** of the heart work properly, and that disturbances in the electrical **system** be promptly and effectively treated.

In accordance with present invention, delivery of the radioactive sources...

...of Norcross, Georgia may be employed in the delivery of the radioactive sources. The Novoste' **system** which is generally shown in Figure 3 and is known as the Beta-Cath" **System** , is described in detail in one or more of the following patents or published applications...

...529,067, and PCT applications WO 00/37137 and WO 01/03761. Although the Novoste **system** is preferred, the broader aspects of the present invention are not limited to the Novoste **system** and other devices for delivering a ...proximity to or contact with cardiac tissue may be used. For example, a wire or **catheter** with a radioactive source or ribbon located at the distal end could also be used to **ablate cardiac** tissue or to form **lesion lines** at specific locations to treat **arrhythmias** as described herein.

Figure 3 depicts the Novostem **System** that may be employed in the present invention in general diagrammatic form for ease of initial understanding. Shown in FIGURE 3 is an elongated **catheter** 20 having a proximal end portion 22 . a distal end portion 24, and at least one source or send **lumen** 26 extending therebetween. The **catheter** is sized for insertion of the distal end portion through the vascular **system** of a patient to a selected area in the heart to be ablated, such as...

...AV node or other site.

This may be carried out, for example, by inserting the **catheter** percutaneously and advancing the **catheter** over a typical **guide wire** 28 into the right atrium and/or the left atrium via transeptal puncture and catheterization.

**Guide wires** and procedures used in advancing such a catheter to the point of **ablation** are well known and will not be discussed in detail.

At the proximal end of the **catheter** , which is located outside the patient in a percutaneous **procedure** such as described above, a transporting and/or loading device 30 is provided for loading...

...as pellets or capsules (also called "seeds") comprising or containing radioactive material, into the send lumen 26 of the catheter 20.

Additional seeds may also be loaded such that the total length of the combined seeds corresponds to at least the length of the lesion to be ablated.

After the radioactive source or source train is loaded, ...via liquid source 32 through a port 34 in the proximal end of the send lumen 26 behind the source (s) . Flow of liquid through the lumen pushes the source (s) along the send lumen to the distal end portion, which is located at the site to be treated. The...

...for moving the sources may be allowed to exit from the distal end of the catheter , but is preferably returned in a parallel return lumen provided in the catheter that communicates at the distal end of the catheter with the send lumen .

After the radioactive source or sources train is located at the desired site, it is...

...pellets, provides an elongated and essentially continuous radiation source that may be used to form lines of ablated tissue through the heart, atrium , wall. The radioactive sources are preferably beta-emitting, although gamma-emitting, x-ray or other...is presently not fully known, but may be ascertained with routine and well know testing techniques that do not require undue experimentation.

After the treatment is complete, the catheter may be removed or shifted to a different treatment position. The radioactive sources are preferably returned to the leading device while the catheter is ...to the patient. To retrieve the radioactive sources, liquid may be forced through the send lumen in a reverse direction to return the treating element to the proximal end and into the loading device, if desired, before removal of the catheter . The reverse flow of fluid may be achieved by forcing liquid under positive pressure through the return lumen in a reverse direction, which forms a closed loop with the send lumen , forcing the sources in a reverse direction to the loading device 30.

Figure 4 illustrates...understanding its function and structure. As seen there, the loading device, as with the preferred catheter has three separate lumen -a guide wire lumen 36 for receiving a guide wire to guide the catheter to the area of the heart to be ablated, a send lumen 38 for hydraulically forcing the source train to the distal end of the catheter and a return lumen 40, which communicates with the send lumen at the distal end of the catheter for retrieving the source train into the loading device. The guide wire lumen may extend through the entire length of the catheter or through only a distal end portion of the catheter between a distal end opening and a side opening

in the **catheter** located proximal to the distal end opening but still in a distal portion of the **catheter** .

The source train is made up of a plurality of radioactive small sources or seeds 42 pre-loaded into a source train **lumen** 43 in radiation-shielding cartridge 44. The loading device 30 includes a receiving recess or station 46 into which the cartridge 44 may be inserted.

Alignment of source train **lumen** 43 with the send **lumen** 38 allows the seeds to be ejected and transmitted along the send **lumen** to the distal end of the **catheter** . For example, a liquid-filled syringe may be attached to the send **lumen** 38 of the loading device to force the source train seeds to the distal end of the **catheter** . To remove the sources after ablation is complete, or to shift the **catheter** position, a syringe or other pressure source may be attached to the return **lumen** 40 of the device to force liquid flow in the reverse direction, returning the source...a single syringe could be used, and the flow switched between the send and return **lumen** , as required.

Figures 5a and 5b show the distal end of a **catheter** that may be employed in carrying out the present invention. The **catheter** has a **guide wire lumen** 48, a send **lumen** 50 and a return **lumen** 52 connectable with the respective **guide wire** , send and return **lumen** of the loading device. The **catheter** is shown with a train 54 of ...The length of the source train 54 may be selected as needed to ablate a **lesion** of the desired length. A single radioactive element or point source may be sufficient to...

...of the AV node. However , a source train of selected length is preferred for forming **linear lesions** or **scar** tissue such as those that may be used in the MAZE **procedure** . Because it may be required to vary the length of the source train, the loading...that the user can retrieve the source train of the length needed for a particular **line** of ablation, or to store radioactive seeds in a way that allows the user to this application.

Figures 7 and 8 illustrate the present invention employing a **guide wire** 58 with a **preformed** tip, shaped as desired, e.g. **curved** to conform to the wall of the heart to be ablated, to provide an active positioning means for the **catheter** . As shown in Figure 7a, the **guide wire** is first inserted through a **guide tube** or sheath 60 into the right atrium 4 (preferably through the Inferior Vena Cava) , where it is positioned against the **atrial** wall at the location to be **ablated** (which may be identified by a **procedure** called mapping).

As seen in Figure 8, the **catheter** 30 in accordance with the present invention is advanced over the **guide wire** 58, through the **guide tube** or sheath 60, until it lies along the surface of the heart to be ablated...

...of

radioactive seeds is advanced (as by hydraulic force) to the distal end of the **catheter**, which lies against the **atrial** wall. The radioactive seed train is allowed to remain in the distal end until sufficient radiation dose is provided to **ablate** a **lumen lesion** along the **line** where the distal end of the **catheter** lies. The radioactive seed train may then be retrieved for repositioning or removal of the **catheter**. Because the radiation sources are not located in the **catheter** during introduction, positioning or withdrawal, overexposure of the heart to radioactivity is minimized.

Figure 7b illustrates, similar to Figure 7a, a guide **wire** of alternative shape. Figure 7b shows a loop, spiral or pig-tail shaped **guide wire** that may be used to form a **line** of ablation around the pulmonary vein.

Although shown as a spiral or pigtail shape, any other suitable shape may also be used to form the **line** of ablation, and the present invention is not limited in its broader aspects to the particular **guide wire** shape. As illustrated, one means of entry into the pulmonary vein is into the right wall, isolating the pulmonary vein(s) from the remainder of the left **atrium**. The spiral or pigtail shape is particularly useful for locating the radiation source **catheter** within a pulmonary vein itself and treating pulmonary vein stenosis by exposing the interior or...

- ...surface of the pulmonary vein to a stenosis-inhibiting dose of ionizing radiation. Alternatively, the **guide wire** portion located in the pulmonary vein could be straight and generally centrally located within the...
- ...It is contemplated that these alternative shapes would be used with a radiation source delivery **catheter** having a sufficiently flexible distal end to conform to the shape of the **guide wire**. The **guide wires** of Figures 7a and 7b could be of any suitable material, such as stainless steel, titanium or nickel-titanium alloy.

Alternatively, the **catheter** itself could have a pre shaped distal end, such as curved, pig-tail or spiral...

- ...the desired position for ablation. This shape could be set into the end of the **catheter** using known **techniques** such as heat setting, molding or the like. With this type of **catheter**, the **guide wire** would tend to straighten the **catheter** during insertion, and withdrawal of the **guide wire** would allow the **catheter** to resume its preset shape. After properly positioned against the wall of the heart...

- ...location to be ablated, the radioactive sources would be inserted into the end of the **catheter** for the ablation treatment.

The **catheter** (see Figure 8) may also have electrode (s) or sensor (s) 61, such as bipolar, carried at

the distal end portion and communicating via conductors extending through the **catheter** to a proximal location outside the patient's body. At least one such electrode is...to the radiation source. Two electrodes or sensors would allow sensing of conductivity across a **line** of ablation to determine if ablation is complete.

Also, the electrodes would allow for direct...

...or

treatment. The electrodes would be connected through one or more conductors extending through the **catheter** to a monitoring or readout device located outside the patient's body.

Further, the **catheter** may include a cooling surface 63 on the distal end portion for cooling selected **cardiac** tissue, for example, to identify the desired site for **ablation** or other radiation treatment. This cooling surface could be based on the Peltier effect, as...

...No. S,529,067, and also connected via one or more conductors extending through the **catheter**. More specifically, **systematic** cooling of selected heart tissue and observation of the effect of cooling on the electrophysiology...identified, the treatment can be immediately carried out by advancing the radiation source through the **catheter** and to the site without further movement of the **catheter** required. This has the potential benefit of better assuring that treatment is being carried out...

...alternative positioning

means for actively and positively positioning the distal end of a radiation delivery **catheter** 62. The **catheter** 62, as shown there, includes at least a source send **lumen** 64 and a parallel fluid return **lumen** 66 extending between the proximal and distal end portions of the **catheter**.

opposed steering wires 68 are embedded in or otherwise attached to the tip end of the **catheter**, 1800 apart, and extend through smaller diameter steering wire **lumens** 70 that extend the length of the **catheter** parallel to the send and return **lumens** for remote control outside the patient's body. By pushing or releasing one steering wire and pulling the other steering wire, the tip end of the **catheter** may be bent or curved in varying degrees toward the wire that is pulled for Figure 9b, or for steering the **catheter** to the desired location in the heart. The **catheter** described above could also be employed with only a single steering wire and steering wire **lumen**, which would allow bending in one direction only.

It is preferable that the steering wires not be located between the radiation source and the **line** of tissue to be ablated, because this may result in attenuation of the radiation or a disturbance in the radiation dose distribution. In an alternative embodiment, the steering wire **lumens** may be positioned



differently in relation to the radiation source and fluid delivery lumens , as shown in Figure 16. The catheter shown there also has four lumens : a radioactive seed send or delivery lumen SL, a fluid return lumen RL, which may alternatively be elliptical rather than round for less pressure and faster seed delivery, and two smaller steering wire lumens WL that are between and offset from (not in alignment with) the other two delivery/return lumens . The two smaller lumens house steering wires that are attached to the distal end of the catheter and give the catheter bi-directional steering capabilities. The steering wires may be embedded within the closed distal end of the steering wire lumens or otherwise attached to the distal end of the catheter . The construction shown in Figure 16 allows essentially an entire side S (180') of the catheter to lie against the cardiac tissue for ablation without interference from the steering wires. All four lumens can' be extruded as a single piece' or can be formed separately and fused together...

...of course  
be a conventional operating mechanism for each at the proximal end of the catheter .

Figures 10a-10c show another positive positioning means for the catheter employing an expandable cage or basket 72 that braces the distal end of the catheter 74 against the heart wall at the place of ablation. As seen in Figure 10...

...between a pair of spaced-apart retainers 78 located on the distal end of the catheter . The retainers 78 may comprise circumferential bands of heat-shrunk plastic or other materials, preferably recessed into the surface of the catheter to provide a generally smooth surface for advancing through a guide tube or sheath.

The retainers tightly hold each end of the spokes, so that the spokes...

...suitable material and are pre-arranged, as by pre-stressing, to expand away from the catheter when the tip end is bent, as shown in Figure 10c, and to return substantially to their original position extending generally parallel to the catheter , as seen in Figures 10a and 10b, when the tip is allowed to return to...

...by the use of a pull wire 79 that extends from the tip of the catheter through a side aperture 77 located in the wall of the catheter at a location spaced from the tip end. By pulling on the wire, the tip...

...the spokes bend to the expanded position. Releasing the pull wire allows the spokes and catheter tip to return essentially to the original position. Although illustrated with the catheter on the ...outside of the basket, the spokes could be arranged around the distal end of the catheter so that the catheter is located within the basket. In such an arrangement, the distal end of the catheter may not be in

direct contact with the heart wall, but closely adjacent or in...

...by coating with a radioactive material, having a radioactive material imbedded in them or other **technique**. In this arrangement, the spokes need not be parallel to one ...another, but may be arranged in such a pattern as desired to form multiple oblique **lines** of ablation within the heart upon deployment of the basket in contact with the heart...

...11a-11c show an alternative basket or nest or cage arrangement for actively positioning the **catheter** tip. In this embodiment, the spokes 76 are preformed or preset to the position shown...their expanded or deployed position (as seen in Figure 11c), bracing the tip of the **catheter** against the heart wall.

In addition to stainless steel or plastic, the spokes in this...that is particularly well suited for forming a basket or cage arrangement to hold the **catheter** tip against the heart wall or in close proximity to it. To remove or reposition the **catheter**, the sleeve would be advanced over the spokes to hold them in the retracted position...

...cage, but other fixation devices such as an expandable balloon, vacuum port(s) in the **catheter** wall or anchors may be used to affix the **catheter** at the desired location. A balloon attached to one side of the **catheter** (extending less than 360°, and preferably less than 180° around the **catheter** shaft) may be used for example to brace the **catheter** against the heart tissue to be ablated. Such a **catheter** would appear similar to that shown in Figure 11, but with a balloon in place of the spokes and with the addition of an inflation **lumen** extending between the proximal and distal end portions of the **catheter** and in fluid communication with the balloon.

Alternatively, one or more vacuum ports may be provided in the **catheter** wall in a manner ...screws or the like may also be used on the distal end portion of the **catheter**, as shown in the above patent, to affix the **catheter** in proximity to or contact with the **cardiac** tissue to be **ablated** or otherwise treated by ionizing radiation from the source.

In addition to the features and functions described above, other aspects of the invention include having the distal end of the **catheter** more flexible than the main body of the **catheter** for improved steerability and/or less tissue trauma. Also, **catheters** may be used with or without guide wires. The pre-shaped guide wires or pre **shaped catheters** may have other shapes in addition to pig-tail or spiral.

It is known that ablation around the pulmonary vein using prior rf ablation **techniques** may result in stenosis, which is a closure, of the pulmonary vein.

Stents have been used, sometimes unsuccessfully, to hold the vein open after an angioplasty **procedure** is performed to, reopen the vein. It has been suggested by others that the Novostem Beta-Cath' **System** may be used to treat or avoid ...example, the basket or cage fixing means may be used to position the radiation delivery

**catheter** at the desired location within the pulmonary vein, with the **catheter** in close proximity to the area of ablation, to diminish the growth of **scar** tissue (a predominant factor in stenosis following damage ...to blood vessels by angioplasty, stents and the like). Or a pigtail or spiral shaped **guide wire** could be used with a radioactive source delivery **catheter** for achieving the same objective.

Figure 12 illustrates employment of a **catheter** of the present invention to form a **line** of ablation or a **lesion** in the **atrial** wall around the ostium of a pulmonary vein. The **catheter** may have a preformed tip that, upon withdrawal of the **guide wire**, forms a circle or **loop** of a size sufficiently large to encircle the ostium of the pulmonary vein. After placing...sufficient length to encircle the ostium would be advanced to the distal end of the **catheter** to form the **lesion** encircling the pulmonary vein. Alternatively a shorter radiation source could be used, and the position of the radiation source periodically changed until a complete **lesion** is formed around the ostium. Although shown ablating a **line** around a pulmonary vein, the above **method** could be used to form a **lesion line** around more than one pulmonary vein simultaneously.

Figures 13a-C illustrate a **catheter** 82 of the present invention with steering wires for changing ...of the distal end. As shown there, a preferably continuous wire 88 is employed. The **catheter** includes two steering wire **lumens** (although a single **lumen** may be used for both wires) that extend between the handle, which is attached to the proximal end of the **catheter**, and the distal end of the **catheter**. One end of the wire extends through one such **lumen** and terminates at the distal end of the **catheter**, where it is attached to the tip 90. The other end of the wire extends through the other **lumen** and also terminates at the distal end of the **catheter**, where it is attached to the tip. The steering wire receiving **lumen** are about 1800 apart so that pulling on one wire while releasing or pushing on...

...other causes the tip to deflect in the direction of the pulled wire. Thus, the **catheter** tip may be deflected in two different and opposed directions as shown in Figures 13b...of this invention. This steering wire construction also is not limited to a radiation source **catheter**, but may be used in any **catheter** that needs to navigate tortuous body passageways, such as cardiology **catheters**.

Figures 14 and 15 show additional features of a modified steering wire and a distal tip **lumen** connector.

Figure 15 shows a steering wire construction that is not limited to a radiation delivery **catheter** or to use in cardiac ablation, and may be employed in other **catheters**, particularly **cardiology catheters**, where navigating a tortuous body **lumen** is necessary.

The **catheter** 98 shown in Figure 15 f or illustrative purposes only is a radiation source delivery **catheter**, such as described generally above. The **catheter** is elongated and flexible, and has a proximal end portion and a distal end portion. The **catheter** includes a radiation source **lumen** 100 and a fluid return **lumen** 102. A single wire, generally at 104, extends through steering wire **lumen** 106 to form steering wire 108, curves at the distal end of the **catheter** around a **lumen** connector 110 and returns through steering wire **lumen** 112 to form steering wire 114. The distal end of the steering wire 104, which curves around the **lumen** connector, may be fixed to the distal tip end of the **catheter** by adhesive, bonding, interference fit, or suitable means or may otherwise be in a fixed non-moving relationship to the **lumen** connector so as to transmit forces applied by the steering wires to the distal tip...

...108 and 114 could be separate and individually attached in the distal tip of the **catheter** while still benefiting from the aspects of the present invention shown in Figure 15. Similarly, although the steering wire **lumens** are shown about 1800 apart, that could also be varied as desired to vary the shape of the bend imparted to the distal end of the **catheter**.

As seen there, one steering wire includes a bend or curve-accommodating segment, generally at...wire - the combination of tension and compression results in smaller radius of curvature.

The illustrated **catheter** 98 in Figure 15 includes another steering wire feature that allows the distal end portion of the **catheter** to be curved in predetermined direction. Steering wire 108 includes a bend 118 that engages against an obstruction 120 located in **lumen** 106 when the wire is pulled, causing the wire to curve at the bend. In...

...accommodating segment, and the obstruction is defined by a plug fused or bonded in the **lumen** 106, and the steering wire 108 slidably extends through the plug. When the steering wire...

...wire to bend in a direction opposed to the bend 118. With this feature, the **catheter** may be caused to bend ...i.e., at the bend 118, and all or some of the portion of the **catheter** distal to bend 118 can remain essentially straight.

The bend feature could, of course...

...in the

same steering wire it is possible to cause the distal portion of the **catheter** to bend in two different directions simultaneously with a relatively small radius of curvatures in...different planes, affording a variety of shapes to the surgeon for navigating through complex body **lumens**, or for positioning the **catheter** against or in proximity to the tissue to be treated.

The illustrated tubular U-shaped **lumen** connector 110 located in the distal tip of the **catheter** connects the source and return **lumens** in fluid communication. The **lumen** connector allows the fluid, which transports the radioactive source to the distal end portion, ...construction and al-so serves to add strength and stability to the end of the **catheter**. Additional features and advantages may be apparent to one skilled in the filed upon review...

#### Claim

A **method** for ablating **cardiac** tissue comprising exposing the **cardiac** tissue to ionizing radiation from an ionizing radiation source in proximity to or contact with the cardiac tissue.

2 The **method** of Claim 1 in which the ionizing radiation source is elongated and essentially continuous, and a **line** of **ablated cardiac** tissue is formed.

3 The **method** of Claim 1 in which the radiation source is brought into proximity to or contact with an endocardial surface.

4 The **method** of Claim I in which the radiation source is brought into proximity or contact with an epicardial surface.

5 The **method** of Claim I in which the radioactive source is held by a fixation device in immediate proximity to or contact with the **cardiac** tissue to be **ablated**.

6 The **method** of Claim 1 comprising positioning a distal end portion of an elongated **catheter** in immediate proximity or contact with cardiac tissue to be ablated and advancing the ionizing of the left **atrium**.

8 The **method** of Claim 1 in which the ionizing radiation source is a beta radiation source.

9 The **method** of Claim 1 including selectively cooling the **cardiac** tissue to identify the tissue to be **ablated**.

10 The **method** of Claim 6 in which the **catheter** includes a cooling surface disposed on the distal end portion and the **method** includes selectively contacting cardiac tissue with the cooling surface to identify the

tissue to be **ablated** .

11 The method of Claim I further comprising sensing an electrophysiological characteristic of the **cardiac** tissue.

12 The **method** of Claim 6 in which the **catheter** includes an electrode on the distal end portion to sense an electrophysiological characteristic of the cardiac tissue.

13 The **method** of Claim 2 in which the elongated radiation source comprises a plurality of individual radiation sources disposed in a **line** to define the elongated source.

14 The **method** of Claim 13 in which the elongated radiation source is advanced along the **catheter** by fluid pressure.

15 The **method** of Claim 6 in which the **catheter** is inserted through the atrial septum.

16 The **method** of Claim 6 in which the distal end portion of the **catheter** is sufficiently flexible to conform to the shape of a **guide wire** , and the **method** includes advancing the distal end portion of the **catheter** along a **guide wire** to the **cardiac** tissue to be **ablated** .

17 The **method** of Claim 16 in which the distal end portion of the **catheter** includes a pre-formed shape that it assumes upon withdrawal of the **guide wire** from the distal end portion.

18 The **method** of Claim 17 in which the pre-formed shape is a spiral.

19 The **method** of Claim 6 further comprising steering the distal end portion of the **catheter** to **cardiac** tissue to be **ablated** .

20 The **method** of Claim 19 wherein the steering comprises adjusting the shape of the distal end portion.

21 The **method** of Claim 6 in which the distal end portion of the **catheter** is held by a fixation device in proximity to or contact with the cardiac tissue to be **ablated** .

22 A method for modifying the conduction characteristics of the AV node of a human heart comprising exposing the **cardiac** tissue comprising the AV node to ionizing radiation from an ionizing radiation source in immediate proximity to or contact with such tissue without completely ablating the AV node.

23 The **method** of Claim 22 comprising positioning a **catheter** in immediate proximity to or contact with the cardiac tissue comprising the AV node and advancing the ionizing radiation source through the **catheter** to a location adjacent to such tissue.

24 The **method** of claim 22 in which the ionizing radiation source is a beta radiation source.

25 The **method** of Claim 22 wherein the conduction characteristic of the AV node is modified to treat reentrant **tachycardia**.

26 The **method** of Claim 22 in which the radioactive source is held by ...immediate proximity to or contact with the cardiac tissue comprising the AV node.

27 The **method** of Claim 22 including selectively cooling the cardiac tissue to identify the tissue to be treated.

28 The **method** of Claim 23 in which the **catheter** includes a cooling surface disposed on the distal end portion and the **method** includes selectively contacting cardiac tissue with the cooling surface to identify the tissue to be treated.

29 Apparatus for treating cardiac tissue comprising an elongated **catheter** including proximal and distal end portions and defining a passageway extending between the end portions ...29 in which the remotely actuated control means comprises a steering wire extending through the **catheter** between the proximal and distal end portions.

31 The apparatus of Claim 29 in which the remotely actuated control means comprises two steering wires extending through the **catheter** between the proximal and distal end portions.

32 The apparatus of Claim 29 in which the distal portion of the **catheter** and adapted to hold the **catheter** against an endocardial surface.

33 The apparatus of Claim 29 in which the fixation device is movable between a retracted position for insertion of the **catheter** and expanded position to hold the **catheter** in the desired location.

34 The apparatus of Claim 29 in which the fixation device includes a plurality of ribs that extend generally parallel to the **catheter** in the retracted position during insertion and are movable to an expanded position to hold the **catheter** in the desired location.

35 The apparatus of Claim 34 in which the ribs are disposed to move away from **catheter** to an expanded position when the distal end portion of the **catheter** is curved, the **catheter** including a remotely controllable pull wire for causing the distal end portion of the **catheter** to curve.

36 The apparatus of Claim 34 in which the ribs are biased to a normally expanded position and the **catheter** includes an axially movable sleeve disposed on the distal

portion of the **catheter** and movable between a first position overlying the ribs and holding them adjacent to the **catheter** and a second position where the ribs are ...Claim 29 further comprising at least one electrode at the distal end portion of the **catheter** to sense an electrophysiological characteristic of cardiac tissue.

39 The apparatus of Claim 38 comprising...

...the fixation device comprises an inflatable member.

41 The apparatus of Claim 33 wherein the **catheter** includes an inflation **lumen** extending ...device includes a balloon carried at the distal end portion and communicating with the inflation **lumen**.

42 The apparatus of Claim 41 wherein the balloon extends less than 3600 around the **catheter** shaft.

43 The apparatus of Claim 29 further comprising an ionizing radiation source located in...proximal end of the return passageway.

45 The apparatus of Claim 29 further comprising a **guide wire** passageway extending through at least the **catheter** distal end portion or a part thereof.

46 The apparatus of Claim 32 wherein the...hold the distal end portion.

48 Apparatus for treating cardiac tissue comprising a flexible elongated **catheter** having a proximal end portion and a distal end portion and defining a passageway extending...

...portions for passage of an ionizing radiation source therealong, the distal end portion of the **catheter** defining pre shaped section disposed to engage the cardiac tissue at a desired location.

49 the distal end portion of the **catheter** is sufficiently flexible to conform to the shape of a **guide wire** and the **method** includes advancing the distal end portion of the **catheter** along a **guide wire** to the cardiac tissue to be treated.

51 The apparatus of Claim 50 in which the pre-shaped section of the **catheter** assumes the pre-shape upon withdrawal of the **guide wire** from the distal end portion.

52 Apparatus for insertion into a chamber of the human...of Claim 53 in which the ionizing radiation source is a beta emitter.

55 A **method** for treating **atrial** fibrillation comprising: defining a plurality of lines of ablated tissue in the wall of the left atrium by exposing selected **cardiac**



tissue to ionizing radiation from an ionizing radiation source in proximity to or contact with the selected tissue..

56 The **method** of Claim 55 in which the ionizing radiation source is elongated and essentially continuous.

57 The **method** of Claim 55 in which the radiation source is brought into immediate proximity or contact with an endocardial surface.

58 The **method** of Claim 55 in which the radiation source is brought into immediate proximity or contact with an epicardial surface.

59 The **method** of Claim 57 in which the radioactive source is held by a fixation device in immediate proximity to or contact with the **cardiac** tissue to be **ablated** .

60 The **method** of Claim 55 comprising positioning a distal end portion of an elongated **catheter** in immediate proximity or contact with **cardiac** tissue to be ablated and advancing the ionizing radiation source through the catheter to a location adjacent to the cardiac tissue to be **ablated** .

61 The **method** of Claim 55 in which the ionizing radiation source is a beta radiation source.

62 The **method** of Claim 56 in which the elongated radiation source comprises a plurality of individual radiation sources disposed in a **line** to define the elongated source.

63 The **method** of Claim 60 in which the elongated radiation source is advanced along the **catheter** by fluid pressure.

64 A **method** for treating pulmonary vein stenosis comprising exposing the interior surface of the pulmonary vein to source in proximity to or contact with such surface.

65 The **method** of Claim 64 in which the ionizing radiation source is elongated and essentially continuous.

66 The **method** of Claim 64 comprising positioning a distal end portion of an elongated **catheter** in immediate proximity or contact with the interior surface of the pulmonary vein and advancing the ionizing radiation source through the **catheter** to a location adjacent to the tissue to be treated.

67 The **method** of Claim 64 in which the ionizing radiation source is a beta radiation source.

68 The **method** of Claim 65 in which the radiation source comprises a plurality of individual radiation sources disposed in a **line** to define the elongated source.

69 The **method** of Claim 66 in which the radiation source is advanced along the **catheter** by fluid pressure.

70 The **method** of Claim 66 in which the **catheter** is inserted through the atrial septum.

71 The **method** of Claim 66 in which the distal end portion of the **catheter** is sufficiently flexible to conform to the shape of a **guide wire**, and the **method** includes advancing the distal end portion of the **catheter** along a **guide wire** to the inside of the pulmonary vein.

72 The **method** of Claim 71 in which the distal end portion of the **catheter** includes a pre-formed shape that it assumes upon withdrawal of the **guide wire** from the distal end portion.

73 The **method** of Claim 72 in which the pre-formed shape is a spiral.

74 A flexible elongated **catheter** comprising a distal end portion and a proximal end portion, first and second **lumen** extending between the proximal and distal end portions, the first **lumen** receiving a steering wire extending between the proximal and distal end portions and fixed to the **catheter** in the distal end portion, the second **lumen** receiving a steering wire extending between the proximal and distal end portions and fixed to the **catheter** at the distal end portion, at least one of the steering wires including a curve-accommodating segment for accommodating curving of the **catheter** in proximity to the segment when push or pull forces are applied to the proximal ends of the steering wires.

75 The **catheter** of Claim 74 in which the steering wires comprised a single elongated wire that extends from the proximal end through the first **lumen** to the distal end portion and through the second **lumen** to the proximal end portion, the wire being continuous in the distal end portion of the **catheter**.

76 The **catheter** of Claim 74 in which the steering wires comprise separate wires.

77 The **catheter** of Claim 74 wherein one of the wires comprises a bend in the distal end portion and the receiving **lumen** includes an obstruction for engaging the bend when the wire is pulled to cause the wire and the distal end portion of the **catheter** to assume a curved shape.

78 The **catheter** of Claim 77 in which the bend and the curve-accommodating segment are located in the same **lumen**.

79 The **catheter** of Claim 75 in which the **catheter** includes third and fourth **lumen** extending between the proximal and distal end portions.

80 The **catheter** of Claim 79 in which the **catheter** comprises a U-shaped **lumen** connector in the distal end

portion connecting the third and fourth **lumen** in a fluidcommunicating relationship.

81 The **catheter** of Claim 77 wherein the bend is proximal to the obstruction.

82 The **catheter** of Claim 81 wherein the curve accommodating segment comprises a plurality of undulations formed in the wire.

83 The **catheter** of Claim 82 wherein the curve accommodating segment comprises a plurality of coils formed in the wire.

84 The **catheter** of Claim 77 in which the bend comprises a generally U-shaped or V-shaped segment in the wire.

85 A flexible elongated **catheter** comprising a distal end portion and a proximal end portion, first and second **lumen** extending between the proximal and distal end portions, the first **lumen** receiving a steering wire extending between the proximal and distal end portions and fixed to the **catheter** in the distal end portion, the second **lumen** receiving a steering wire extending between

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00960446 \*\*Image available\*\*

**TWIN COAXIAL CATHETERS FOR RF PULMONARY VEIN ABLATION  
SYSTEME DE CATHETER D'ABLATION ET DE CARTOGRAPHIE HAUTE RESOLUTION POUR  
SUPPRESSION DE FOYERS DANS LES VEINES PULMONAIRES**

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Detailed Description  
Claims

Detailed Description

... atrial fibrillation ("AF"), a procedure published by Cox et al. and known as the "Maze **procedure**" involves the formation of continuous atrial incisions to prevent atrial reentry and to allow sinus impulses to activate the entire myocardium. While this **procedure** has been found to be successful, it involves an intensely invasive approach. It is more desirable to accomplish the same result as the Maze **procedure** by use of a less invasive approach, such as through the use of an appropriate EP **catheter system** providing RF ablation therapy. In this therapy, transmural **ablation** lesions are formed in the **atria** to prevent **atrial** reentry and to allow sinus impulses to activate the entire **myocardium**.

One such EP **catheter system**, as disclosed in U. S. Patent Nos. 6,059,778 and 6,096...

...includes a plurality of spaced apart band electrodes located at the distal-end of the **catheter** and arranged in a **linear** array. The band electrodes are positioned proximal heart tissue. RF energy is applied through the electrodes to the heart tissue to produce a series of long **linear lesions** 10 similar to those produced by the Maze **procedure**.

As previously mentioned, cardiac arrhythmia, such as atrial **fibrillation**, may be focal in nature. The foci, defined by regions exhibiting a consistent and centrifugal pattern of electrical activation, may act as either a trigger of atrial **fibrillation** **paroxysmal** or may

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even sustain **fibrillation** . Such focal arrhythmia are known to originate from a tissue region along 1 5 the pulmonary veins of the left atrium, and more particularly in the superior pulmonary veins.

**Procedures** for the treatment of focal **arrhythmia** involving the pulmonary vein generally require the use of two separate **catheter systems** - a mapping **catheter system** for locating the foci and an ablation **catheter system** for ablating the foci. Both **catheter systems** include their respective mapping or ablation catheter and either a guiding catheter or a guide **wire** for introducing the catheter into the left **atrium** of the heart. During a typical **procedure** , the mapping **catheter** is first introduced into the left atrium through a puncture in the septum between the...

...left atria. The mapping catheter is then guided into the pulmonary vein.

While the mapping **catheter** is still within the heart, the ablation **catheter** is introduced into the left **atrium** through either the same puncture as the mapping **catheter** or a separate puncture.

Using the mapping **catheter** , the foci of the arrhythmia is located using any of several well known mapping **techniques** . After it is determined that the foci are located within the pulmonary vein, the ablation **catheter** is positioned either in the pulmonary vein or around the pulmonary vein ostium and the tissue is ablated. The procedure thus described requires the simultaneous placement of two separate **catheters** into the left **atrium** through either one or two separate introduction paths. In the case of the left atrium two **catheters** through a single puncture or two separate punctures increases patient trauma. It also increases the...  
...of the septum.

Hence, those skilled in the art have recognized a need for a **catheter system** having two independent **catheters** , each capable of being introduced into the heart via a single transseptal introduction path. The need for a combined mapping and ablation **catheter system** for use in the pulmonary vein has also been recognized. The invention fulfills these needs a combination mapping and I O ablating **catheter system** for use during electrophysiological **procedures** in and around various biological sites, including the pulmonary veins.

In a first aspect, the invention relates to a **catheter system** that includes an outer **catheter** having a lumen therethrough and a distal-end region carrying a first electrode **system** . The **catheter system** also includes an inner **catheter** that is sized to fit within and slide through the **lumen** of the outer **catheter** . The inner **catheter** has a distal-end region carrying a second electrode **system** .

By providing an outer **catheter** having a **lumen** through which a separate inner **catheter** may slide, the invention allows for the simultaneous placement of two separate **catheters** into a biological site through a single introduction path. As such, the likelihood of damaging ...

...substantially reduced.

In detailed aspects of the invention, either one or both of the outer **catheter** and inner **catheter** further include a tendon having a distal end attached to the distal-end region of the respective **catheter** and a

proximal end exiting the proximal end of the **catheter**. The tendon is attached such that movement of the tendon along the length of the **catheter** causes the distal end region of that **catheter** to curve. In another detailed aspect, the outer **catheter** further comprises a shaped-memory stylet for imparting a preshaped curve to the distal-end region of the outer **catheter**. In another further detailed aspect, the preshaped curve has a radius of curvature and the **catheter** further comprises a tendon having a distal end attached to the distal end of the **catheter** and a proximal end exiting the proximal end of the **catheter**. The tendon is attached such that movement of the tendon along the length of the **catheter** decreases the radius of curvature.

In another detailed facet of the invention, the outer **catheter** includes an outer tubular member and an inner tubular member slidably disposed within the outer tubular member. The inner tubular member defines the lumen of the outer **catheter**. The other **catheter** also includes a plurality of outwardly bendable segments. The segments are secured at their distal end. Movement of the inner tubular member causes the segments to bend outward.

In another aspect, the invention relates to a **catheter system** that includes an outer **catheter** having a tubular wall defining a lumen. The tubular wall includes a sidewall orifice.

The outer **catheter** also includes a distal-end region carrying a first electrode **system** and a proximal-end region. The **catheter system** further includes an inner **catheter** sized to fit within the lumen of the outer **catheter** and to slide therein. The inner **catheter** is also sized to fit through the sidewall orifice. The inner **catheter** has a distal-end region carrying a second electrode **system**.

In a detailed facet of the invention, the tubular member comprises a resiliently deformable junction section between the distal end region and the proximal end region...

...of the proximal-end region of the tubular wall. In another detailed aspect, the outer **catheter** further includes a tendon having a distal end attached proximate the inner wall of the tubular wall. In yet another detailed aspect, the outer **catheter** includes a shaped-memory stylet for imparting a generally circular curve to the distal-end region of the tubular wall. The curve lies substantially within a first plane. The inner **catheter** also includes a shaped-memory stylet for imparting a generally circular curve to the distal-end region of the inner **catheter**. This curve lies substantially within a second plane that is substantially parallel to the first plane.

In another detailed facet of the invention the first electrode **system** and the second electrode **system** each comprise a plurality of band electrodes positioned along the length of their respective distal-end region. The **catheter system** further comprises an alignment **system** that is adapted to align the curved distal-end region of the inner **catheter** with the curved distal-end region of the outer **catheter** such that the band electrodes of the respective **catheters** are aligned with each other.

In another further detailed aspect, the alignment **system** comprises a pair of markers, each visible under fluoroscopy. One marker is carried on the proximal region of the inner **catheter** while the other marker is carried on the proximal region of the outer **catheter**.

In another further detailed aspect, the alignment **system** comprises a groove along the outer surface of the proximal region of the inner

**catheter** and a complementary protrusion along the inner surface of the outer **catheter** .

In another facet, the invention relates to a **method** of performing an electrophysiological **procedure** on biological tissue within a biological site. The **method** includes positioning a first **catheter** , having a distal-end region carrying a first electrode **system** , within the biological site proximate the biological tissue. The **method** further includes sensing electrical activity within the tissue through the first electrode **system** and processing the electrical activity to identify the origin of an electrophysiological condition. The **method** further includes guiding a second **catheter** , having a distal-end region carrying a second electrode **system** , via the first **catheter** , **15** into the biological site. The **method** also includes positioning the second **catheter** such that the second electrode **system** is adjacent the identified origin and applying energy to the second electrode **system** to ablate the identified origin.

In a detailed aspect of the invention, the first **catheter** includes a tubular wall defining a **lumen** and guiding the second **catheter** includes sliding the second **catheter** through the **lumen**.

In a further detailed facet, positioning the second **catheter** such that the second electrode **system** is adjacent the identified source includes sliding the second **catheter** through the **lumen** until the second electrode **system** is substantially coincident with the first electrode **system** and repositioning the first **catheter** relative to the second **catheter** to expose the second electrode **system** . In another detailed aspect, the second **catheter** includes a tubular wall defining a **lumen** and guiding the second **catheter** includes sliding the second **catheter** over the first **catheter** . In a further detailed aspect, positioning the second **catheter** such that the second electrode **system** is adjacent the identified source includes sliding the second **catheter** over the first **catheter** until the second electrode **system** is coincident with the first electrode **system** .

In another facet, the invention relates to a **method** of performing an electrophysiological **30 procedure** on biological tissue proximate a pulmonary vein. The **method** includes positioning a first **catheter** , having a distal-end region carrying a first electrode **system** , near the ostium of the pulmonary vein and guiding a second **catheter** , via the first **catheter** , into the pulmonary vein. The second **catheter** has a distal-end region carrying a second electrode **system** . The **method** further includes sensing electrical activity within the pulmonary-vein tissue through the first electrode **system** , processing the electrical activity to confirm the existence of an abnormal ...condition originating within the pulmonary vein and upon confirmation, applying energy to the first electrode **system** to ablate the tissue near the ostium.

In a detailed facet of the invention, the first **catheter** further includes a resiliently deformable shaped-memory stylet for imparting a generally circular curve to the distal-end region of the first **catheter** and positioning the first **catheter** near the ostium of the pulmonary vein includes the steps of straightening the distal-end...stylet for imparting a generally circular curve to the distal-end region of the second **catheter** and positioning the second **catheter** within the pulmonary vein includes the steps of straightening the distal-end region to allow contact with the tissue defining the vein **lumen** .

In another aspect, the invention relates to a **catheter system** including a **catheter** sheath carrying a circumferentially expandable member at its distal end. The **catheter system** further includes a first electrode **system** positioned on the expandable member and a second electrode **system** positioned on the expandable member, proximal the first electrode **system**.

In a detailed aspect of the invention, the expandable member includes a distal segment with...

...segment with a second expandable diameter greater than the first expandable diameter. The first electrode **system** is positioned at the distal segment and the second electrode **system** positioned at the proximal segment. In further detailed aspects either one or both of the first electrode **system** and second electrode **system** includes a plurality of electrode elements arranged to form a circumferential band around the expandable member.

In another aspect, the invention relates to a **method** of performing an electrophysiological **procedure** on biological tissue proximate a pulmonary vein. The **method** includes positioning a circumferentially expandable member having a distal-end region with a first electrode **system** and a proximal-end region with a second electrode **system** in the heart such that ...proximal-end region is adjacent the tissue defining the ostium of the pulmonary vein. The **method** also includes expanding the circumferentially expandable member such that the first electrode **system** contacts the tissue defining the pulmonary vein and the second electrode **system** contacts the tissue defining the ostium, sensing electrical activity within the pulmonary-vein tissue through the first electrode **system** and processing the electrical activity to confirm the existence of an abnormal electrophysiological condition originating within the pulmonary vein.

The **method** further includes applying energy to the first electrode **system** to ablate the tissue IO near the ostium upon confirmation of the existence of...

...the features of the invention.

#### 5 BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a **catheter system** configured in accordance with one embodiment of the invention including a mapping **catheter** slidably positioned within an open- lumen

ablation **catheter** ;

FIG. 2 depicts the **catheter system** of FIG. 1 positioned near the ostium of a vein with the ablation **catheter** retracted to exposed the mapping **catheter** such that the mapping **catheter** may locate the focal origin of an **arrhythmia** ;

FIG. 3 depicts the **catheter system** of FIG. 2 positioned near the ostium of a vein with the ablation **catheter** advanced to coincide with the focal origin previously located by the mapping **catheter** ;

FIG. 4 depicts the distal-end region of an alternate configuration of the **catheter** of FIG.

1 wherein the ablation **catheter** is slidably positioned within an open-lumen mapping **catheter** ; FIG. 5 depicts the **catheter system** of FIG. 4 positioned near the ostium of a vein with the mapping **catheter**



advanced over the ablation catheter such that the mapping catheter may

locate the focal origin of an arrhythmia ;

FIG. 6 depicts the catheter system of FIG. 5 positioned near the ostium of a vein with the mapping catheter retracted to allow the ablation catheter to coincide with the focal origin

previously located by the mapping catheter ;

FIG. 7 is a side view with partial cutaway of a catheter system configured in accordance with another embodiment of the invention including an open-lumen ablation catheter having a precurved distal-end region (shown straightened by a guidewire), a steering system and a sidewall orifice and a mapping catheter sized to fit within the ablation catheter and having a normally curved distal-end region (shown straightened);

FIG. 8 is an isometric view of the catheter system of FIG. 7 with the distal-end region 10 of the ablation catheter assuming its normally curved shape and the distal-end region of the mapping catheter advanced through the sidewall orifice to assume its normally curved shape; FIG. 9A is a sideview, with partial cutaway of the ablation catheter of FIG. 7 showing the distal-...in a plane substantially perpendicular to the axis of the proximal-end region of the catheter ;

15 FIGS. 9A and 9B are side views of the ablation catheter of FIG. 9A showing the normally curved distal end region deflected by the steering mechanism...

...plane at an angle relative to the axis of the proximal-end region of the catheter .

FIG. 10A depicts the catheter system of FIG. 7 deployed near the ostium of a vein with the distal-end region of the ablation catheter straightened by a guidewire ; FIG. 10B depicts the catheter system of FIG. 10A with the guidewire removed, the distal-end region of the ablation catheter in its normally curved state and the mapping catheter

positioned within the ablation catheter ;

FIG. 10C depicts the catheter system of FIG. 10B with the distal-end region of the mapping catheter extending through the orifice of the ablation catheter and in its normally curved state;

FIG. 11 is a cross-sectional side view of a catheter system configured in accordance with another embodiment of the invention including an open-lumen ablation catheter having an expandable distal-end region (shown collapsed) and a mapping catheter sized to fit within the ablation catheter and having a normally curved distal-end region (shown straightened); FIG. 12 is an isometric view of the catheter system of FIG. 11 with the distal-end region of the ablation catheter expanded and the mapping catheter advanced through the lumen to assume its normally curved shape;

FIG. 13A depicts the catheter system of FIG. 11 being deployed near the ostium of a

vein with the ablation catheter being guided over a guidewire;

FIG. 13B depicts the catheter system of FIG. 13A with the guidewire removed, the distal-end region of the ablation catheter expanded and the mapping catheter positioned within the ablation catheter ;

FIG. 13C depicts the catheter system of FIG. 13B with the distal-end region of the mapping catheter extending through the top of the ablation catheter to assume its normally curved shape;

FIG. 14 depicts a **catheter system** configured in accordance with another embodiment of the invention having an expandable member (shown collapsed) carrying a mapping electrode **system** at its distal end and an ablation electrode **system** near its proximal end; FIG. 15 depicts the **catheter** of FIG. 14 with the radially expandable member expanded and deployed within a vein; and FIG. 16 depicts a **catheter system** configured in accordance with another embodiment 5 of the invention having a radially expandable member (shown expanded) and carrying a framework having a mapping electrode **system** at its distal end and an ablation electrode **system** near its proximal end.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings...

...like or corresponding elements among the several figures, in FIG. 1 there is shown a **catheter system** 10 including an outer ablation **catheter** 12 having a lumen throughout and an inner mapping **catheter** 14 configured to fit and slide within the lumen of the outer ablation **catheter**.

The **catheters** 12, 14 may be of various sizes depending on the intended use of the **catheter system** 10. In one configuration of a **catheter system** intended for use within the heart, and particularly, the pulmonary vein, the outer ablation **catheter** has an outside diameter of 2.39 millimeters (0.094 inches) (7 French) and the inner mapping **catheter** has an outside diameter of 1.67 millimeters (0.0657 inches) (5 French).

Electrically connected to the outer ablation **catheter** 12 is an energy generator/ **processor** 16. The energy generator/ **processor** 16 is adapted to provide energy to an ablation electrode **system** 18 located at the distal-end region 20 of the outer ablation **catheter** 12 and to monitor the temperature at the ablation electrode **system**. Electrically connected to the inner mapping **catheter** 14 is a mapping **processor** 22 adapted to receive electrical signals from a mapping electrode **system** 24 located at the distal-end region 26 of the inner mapping **catheter**. Details regarding the ablation electrode **system** 18, the mapping electrode **system** 24 ...respective electrical connections are provided below.

With continued reference to FIG. 1, the inner mapping **catheter** 14 includes a **catheter** handle 28 attached to a proximal end 30 of a mapping **catheter** sheath 32. Housed within the mapping **catheter** sheath 32 are a first steering tendon 36 and a second steering tendon 38. The first steering tendon 36 and the second steering tendon 38 exit the proximal end of the **catheter** sheath 32 and enter the **catheter** handle 28. Within the **catheter** handle 28, the first 36 and second 38 steering tendons attach to a steering controller distal-end region 26 of the inner mapping **catheter** 14.

With further reference to FIG. 1, the profile of the distal-end region 26 of the mapping **catheter** sheath 32 can be adjusted by rotating the steering controller 40. The steering controller 40 can be rotated by rotating a knob 42 either clockwise or counterclockwise. Rotating...region 26. Although FIG. 1 depicts the handle 28 being used with a dual-profile **catheter** with two steering tendons 36, 38, the handle is also functional for single-profile **catheters** with a single steering tendon.

The ablation electrode **system** 18 includes one or more band electrodes 48 arranged in a **linear** array. In a preferred embodiment, the ablation electrode **system** 18 includes three, 3 millimeter wide band electrodes spaced 4 millimeters apart. A plurality of feed wires (not shown) extend through wire **lumen** (not shown) running the length of the ablation **catheter** sheath 34. The wires are electrically connected to the ablation electrodes 48 at their distal...

...at their proximal ends. The electrical connector 49 provides the interface between the energy generator/ **processor** 16 and the lead wires. The lead wires transfer energy from the energy generator/ **processor** 16 to the band electrodes 48. The lead wires may also provide temperature signals to the energy generator/ **processor** 16.

The mapping electrode **system** 24 includes a plurality of band electrodes 50 and a tip electrode 51 arranged in a **linear** array. The band electrodes 50 are spaced close together for highresolution and in a preferred embodiment...

...spaced 1 millimeter apart. A plurality of lead wires (not shown) extend through the mapping **catheter** sheath 32. The wires are electrically connected to the mapping electrodes 50, 51 at their...

...The electrical connector provides the interface between the mapping processor 22 and the lead wires. The lead wires transfer electrical signals to the mapping **processor**.

To assist in steering the **catheter** **system** 10 through the patient's vascular **system** and to assure proper placement of the ablation electrode **system** 18, the distal-end region 26 of the mapping **catheter** sheath 32 is made more rigid than the distal-end region 20 of the ablation 10 **catheter** sheath 34. This may be accomplished, for example, by forming the distal-end region 26 of the mapping **catheter** sheath 32 of a higher durometer than the distal-end region 20 of the ablation **catheter** sheath 34. As such, the distal-end region 20 of the outer ablation **catheter** 12 assumes the shape of the distal-end region 26 of the inner mapping **catheter** 14.

To prevent fluid from entering the space between the inside wall of the outer ablation 15 **catheter** 12 and the outside surface of the inner mapping **catheter** 14, a seal (not shown) is included in the outer ablation **catheter**. The seal is a soft rubber short-length **tubing** or O-ring formed of an elastomeric material, e. g., silicon, Santoprene, Viton, and is adhered to the inside diameter of the outer ablation **catheter** 12 **lumen** near the distal end. The seal forms a tight seal against the outer surface of the inner mapping **catheter** 14. The seal is pliable enough to allow for movement of the outer ablation **catheter** 12 relative to the inner mapping **catheter** 14 yet rigid enough to function as a seal. The outer ablation **catheter** 12 also includes a locking mechanism 47 for locking the outer ablation **catheter** to the inner mapping **catheter** 14. An example of one such locking mechanism is described in U.S. application serial...

...incorporated by reference.

While the operational descriptions to follow focus on the use of the **catheter** **system** 10 for treating focal arrhythmias originating within and around the pulmonary vein, the **system** may be used for treatment of other locations both within and outside of the heart. For **procedures**

not involving the pulmonary vein, the **catheter system 10** may be initially placed within the subject biological site using the steering **system** of the inner mapping **catheter 14**. In such 30 placement **procedures**, the outer ablation **catheter 12** and the inner mapping **catheter 14** are positioned relative to each other such that their distal ends are substantially aligned. The **catheters 12, 14** are then introduced into a patient's vascular **system** and are guided therethrough and into the desired biological site, using the mapping **catheter's** steering **system**. For **procedures** involving the pulmonary vein, the **catheter system 10** may be initially placed within the left atrium through a transseptal approach using a guiding sheath (not shown). Once positioned, the guiding sheath and the **catheter system 10** are moved relative to each other to expose the distal end regions 20, 26 of the **catheter system 10**.

With reference to FIG. 2, once the outer **ablation catheter 12** and the inner mapping **catheter 14** are positioned in the left atrium near the pulmonary vein 52, the outer **ablation catheter** is retracted in the proximal direction relative to the inner mapping **catheter** to expose the distal-end region 26 of the inner mapping **catheter**. The distal-end region 26 is guided into the vein and is positioned against the tissue 56 defining the vein lumen. The profile of the distal-end region 26 of the inner mapping **catheter 14** may be deflected using the steering **system** to ensure better contact between the mapping electrode **system 24** and the tissue 56.

Electrical signals traveling through the tissue 56 are sensed by the mapping electrode **system 24** and are sent to the mapping **processor 22** (FIG. 1) for analysis. The mapping electrode **system 24** is repositioned and then the **process** is repeated until the foci 54 of the arrhythmia are located.

With reference to FIG. 3, once the foci 54 are located, the outer **ablation catheter 12** is advanced distally over the inner mapping **catheter 14** until the ablation electrode **system 18** is at or near the foci 54. Because the distal-end region 20 of the outer **ablation catheter 14** is more pliable than the inner mapping **catheter 12**, it assumes the shape of the mapping **catheter** and is thus placed at or near the foci 54. In a preferred embodiment, markers (not shown) are placed on both the inner mapping **catheter 14** and outer **ablation catheter 12**. Under fluoroscopy, the markers are used to align the ablation electrode **system 18** with the mapping electrode **system 24** and hence with the foci 54. Once properly positioned, energy is applied to the ablation electrode **system 18** from the energy generator/ **processor 16** (FIG. 1). In a preferred embodiment the energy generator/ **processor 16** provides RF energy. In alternate embodiments, other forms of energy may be applied such as cryoablation...pulmonary vein 52. In the embodiment shown, the RF energy passes through the ablation electrode **system 18** into the tissue 56 at or near the foci 54 to ablate the tissue...

...reference to FIG. 4, in an alternate configuration of this embodiment of the invention, the **catheter system 10** includes an inner ablation **catheter 58** having an ablation electrode **system 60** and all outer mapping **catheter 62** having a mapping electrode **system 64**. The inner ablation **catheter 58** includes a steering mechanism like that described with reference to the inner mapping **catheter 14** (FIG. 1) of the previous embodiment.

In operation, as shown in FIG. 5, once the outer mapping **catheter 62** and the inner ablation **catheter 58** are positioned in the heart, the

distal-end region 66 of the outer mapping **catheter** 62 is guided into the vein 52 and is positioned against the tissue 56 defining...

...vein himen. Electrical signals traveling through the tissue 56 are sensed by the mapping electrode **system** 64 and are sent to the mapping **processor** 22 (FIG. 1) for analysis. The mapping electrode **system** 64 is repositioned and then the **process** is repeated ...located.

With reference to FIG. 6, once the foci 54 are located, the outer mapping **catheter** 62 is retracted proximally relative to the inner ablation **catheter** 58 to expose the ablation electrode **system** 60 at or near the foci 54. The distal-end region 68 of the inner ablation **catheter** 58 is positioned such that it contacts the tissue 56 at or near the foci 54. The distal-end region 68 of the ablation **catheter** 58 may be deflected using the steering **system** to ensure adequate contact between the ablation electrode **system** 60 and the tissue 56. Once adequately positioned, energy is applied to the ablation electrode **system** 60 by the energy generator/ **processor** 16 (FIG. 1) to ablate the tissue 56 at or near the foci 54.

In other embodiments of the invention the **catheter system** includes an ablation **catheter** that is specially configured to ablate a circumferential band of tissue near the entry of the pulmonary vein himen. A "circumferential band" as used herein is a continuous **line** that is traced around a region of space and which starts and ends at substantially the same location.

The **catheter system** also includes a mapping **catheter** that is also specially configured to circumscribe a band of tissue within the vein **lumen**.

With reference to FIG. 7 one such **catheter system** 80 includes an outer ablation **catheter** 82 having a tubular wall 84 defining a lumen 86. The lumen 86 extends between...

...The tubular wall 84 has a distal-end region 90 that carries an ablation electrode **system** 92. In a preferred embodiment, the ablation electrode **system** 92 includes a plurality of band electrodes 94 and a tip electrode 96. The lumen 86 extends through the tip electrode 92 to allow for placement of the ablation **catheter** 82 over a guidewire 98. In an alternate configuration the ablation **catheter** 82 is guided through a sheath. In such a configuration, the need to extend the lumen 86 through the tip electrode 92 is eliminated. The tubular wall 84 includes an orifice ...

...102 located between the distal-end region 90 and the proximal-end region 104.

The **catheter system** 80 further includes an inner mapping **catheter** 106 configured to fit into and slide within the lumen 86 of the outer ablation **catheter** 80 and to ...fit through the orifice 100 contained within the tubular wall 84. The inner mapping **catheter** 106 includes a tubular wall 108 having a distal-end region 110 that carries a mapping electrode **system** 112.

In a preferred embodiment, the mapping electrode **system** 112 includes a plurality of band electrodes 114 and a tip electrode 116.

...in FIG. 8, the distal-end regions 90, 110 of both the ablation

**catheter 82** and the mapping **catheter 106** respectively are formed such that they normally assume an arc shape that nearly forms ...0 assume their normally arced shape, the electrodes 114, 116 carried by the mapping **catheter 106** and the electrodes 94, 96 carried by the ablation **catheter 1582** circumscribe a predefined circle or partial circle. The arc of the ablation **catheter 82** is sized to fit around all or part of a vein ostium while the arc of the mapping **catheter 110** is sized to fit within the vein. **Catheters** having different sized arcs may be used depending on the particular anatomy being treated. In...

...by shaped-memory nitinol stylets (not shown) carried within the tubular walls 84, 108 of the **catheters** at the distal-end regions 90, 110. Alternatively, the shaped-memory may be provided by heatsetting the polymer of the **catheter**.

In an alternate configuration, the tubular walls 84, 108 of the **catheters** each include a lumen (not shown) that carries a tendon 85, 109. The distal end of the ablation **catheter** tendon 85 is attached to the distal tip of the tubular wall 84 near the...

...in FIG. 1. Applying tension to the tendons 85, 109 along the length of the **catheter** shaft causes the radius of curvature of the respective distal-end regions 90, 110...normally assume their arced shapes, the distal-end regions 90, 110 of both **catheters 82, 106** are resiliently deformable and may assume a **linear** shape when forced to. More specifically, as shown in FIG. 7, the distal-end region 90 of the ablation **catheter 82** assumes a **linear** shape when it is positioned over a **guidewire 98**. With regard to the mapping **catheter 106**, its distal-end region 110 assumes a **linear** shape when it is positioned within the **lumen 86** of the ablation **catheter 82**.

With continued reference to FIG. 7, the junction section 102 positioned between the distal-end region 90 and the proximal-end region 104 of the ablation **catheter 82** is formed of a resiliently deformable material, such as Pebax, Nylon or Urethane. The junction section 102 is normally bent to an angle of approximately 90 degrees. When the junction section 102 is in its normally bent...

...87 of the proximal-end region 104 (FIG. 7) of the tubular wall 84. The mapping **catheter 106** is similarly configured to include a bend like that of the ablation **catheter 82**.

In a preferred embodiment, the ablation **catheter 82** (FIG. 7) includes a steering mechanism for deflecting the distal-end region 90. In...tendon 120, 122, the arc formed by the distal-end region 90 of the ablation **catheter 82** lies in a plane substantially perpendicular to the axis 87 of the ...120 (FIG. 9A), the arc formed by the distal-end region 90 of the ablation **catheter 82** is deflected in a first direction such that the arc lies in a plane...

...122 (FIG. 9A), the arc formed by the distal-end region 90 of the ablation **catheter 82** is deflected in a second direction, opposite ... the proximal-end region 104.

With reference to FIG. 1 OA, in operation, the ablation **catheter 82** is introduced into a patient's vascular **system** and is guided therethrough and into the heart using a **guidewire 98**.

As is meant to be shown in FIG. 1 OA, the **catheter 82** has been advanced into the left atrium of the patient's heart through the septum, and is

now directed towards the pulmonary vein that connects to the left atrium of the heart. Alternatively, the ablation catheter 82 may be guided into the heart through a sheath. With reference to FIG. 10B, once the ablation catheter 82 is positioned in the heart, the ablation catheter and guidewire 98 are moved relative each other such that the distal-end region 90 of the ablation catheter 82 is no longer constrained to a straight position by the guidewire 98 and assumes its normally arced shape. The ablation electrode system 92 is then positioned at the ostium 124 of the pulmonary vein. Once the ablation electrode system 92 is positioned, the mapping catheter 106 is guided through the lumen 86 of the ablation catheter 82 toward the ...tubular wall 84. As previously mentioned, the distal-end region I 10 of the mapping catheter 106 is formed of a material less rigid than the proximal-end region of ablation catheter 82. As such the normally arced shape of the distal-end 15 region I 10 assumes the shape of the proximal-end region 104 of the ablation catheter 82.

As shown in FIG. 10C, as the distal-end region I 10 of the mapping catheter 106 passes through the orifice 100 and is no longer constrained by the proximal-end region 104 of the ablation catheter 82, it assumes its normally arced shape. The distal-end region II 0 is advanced into the pulmonary vein 126 until the mapping electrode system 112 contacts the tissue 128. Electrical signals, i. e., pulmonary vein potentials, are sensed by the mapping electrode system 112 and sent to the mapping processor where they are analyzed to determine if the pulmonary vein contains an arrhythmogenic origin for atrial arrhythmia.

If it is determined that the pulmonary vein contains an arrhythmogenic origin 130, the ablation electrode system 92 is positioned such that it circumferentially engages the ...tissue around the pulmonary vein ostium 124. Energy is then applied to the ablation electrode system 92 to ablate the tissue around the ostium 124 to thereby form a circumferential lesion 132 which blocks electrical conduction from the arrhythmogenic origin 130 along the pulmonary vein 126 wall into the left atrium. To ensure the formation of a continuous circumferential lesion 132, energy may be applied to the ablation electrode system 92 using a combination unipolar/bipolar technique and/or phasing technique such as that described in U.S. Patent Nos.

6,050,994 6,059,778...hereby incorporated by reference.

With reference to FIG. 8, in a preferred embodiment of the catheter system 80 the distal-end region I 10 of the mapping catheter 106 and the distal-end region 90 of the ablation catheter 82 may be positioned relative each other such that the mapping electrodes 114, 116 align with the ablation electrodes 94...may be accomplished using a marker visible under fluoroscopy located on the shafts of the catheter. Using a marker allows for the mapping catheter 106 and the ablation catheter 82 to rotate relative each other.

Alternatively, alignment of the electrodes 94, 96, 114, 116 may be accomplished by a guide system carried by the catheter system. The guide system may include a linear groove (not shown) along the interior of the proximal-end region 104 of the ablation catheter 82 and a complimentary linear protrusion (not shown) along the exterior of the proximal-end region of 15 the mapping catheter 106. During deployment of the mapping catheter 106 through the ablation catheter 82, the protrusion is positioned within the groove to align the catheter such that their respective electrodes are aligned. Alternatively, the

groove may be carried by the mapping **catheter** 106 and the protrusion by the ablation **catheter** 82. In this case, the **catheters** 82 and 106 are not free to rotate relative to each other.

With reference to FIG. 11, in another embodiment of the invention, a **catheter system** 140 includes an outer ablation **catheter** 142 having an expandable ablation electrode **system** 144. The ablation **catheter** 142 includes an outer tubular member 146 and an inner tubular member 148 slidably disposed within the outer tubular member. The inner tubular member 148 defines an outer- **catheter lumen** 150. The outer ablation **catheter** 142 further includes a plurality of outwardly bendable segments 152 that, in this embodiment, take...width of the strips 152 depends on the number required to be placed about the **catheter**. The more strips that are required, the narrower each one may be. However, there may...each of the segments 152. Lead wires (not shown) run the length of the ablation **catheter** 142 and connect the ablation electrodes 160 to an energy generator/ **processor** such as that shown in FIG. 1. The lead wires are carried by a **lumen** (not shown) contained within the outer tubular member 146 and the bendable segments 152.

The **catheter system** 140 further includes an inner mapping **catheter** 162 configured to fit and slide within the outer- **catheter lumen** 150. The inner mapping **catheter** 162 includes a tubular wall 164 having a distal-end region 166 that carries a mapping electrode **system** 168.

In a preferred embodiment, the mapping electrode **system** 168 includes a plurality of band electrodes 170 and a tip electrode 176. The distal...

...complete circle as shown in FIG. 12. The distal-end region 166 of the mapping **catheter** 162 is less rigid than the inner tubular member 148 of the ablation **catheter** 142 and assumes the shape of the inner tubular member when it is positioned therein. The configuration of the mapping **catheter** 162 is similar to that of FIG. 7.

With reference to FIG. 13A, in operation, the ablation **catheter** 142 is introduced into a patient's vascular **system** and is guided therethrough and into the heart using a **guidewire** 174.

Alternatively, the ablation **catheter** 142 may be guided into the heart through a sheath. Once the ablation **catheter** 142 is positioned in the heart, the **guidewire** 174 is removed and the inner **tube** 148 (FIG. 11) of the ablation **catheter** 142 is retracted relative to the outer **tube** 146, thereby causing the ablation electrode **system** 144 to assume its expanded form as shown in FIG. 13B. The ablation electrode **system** 144 is then positioned at the ostium 124 of the pulmonary vein 126, such that the ablation electrodes 160 contact the tissue 128.

Once the ablation electrode **system** 144 is positioned at the pulmonary vein ostium, the mapping **catheter** 162 is guided through the **lumen** 150 (FIG. 11) of the ablation **catheter** 142.

As previously mentioned, the mapping **catheter** 162 is formed of a material less rigid than the inner tubular member 148 of the ablation **catheter** 142, as such the normally arched shape of the distal-end region assumes the shape...

...148.

As shown in FIG. 13C, as the distal-end region 166 of the mapping **catheter** 162 passes through the top of the inner tubular member 148, it



assumes its normally...

...The distal-end region 166 is advanced into the pulmonary vein until the mapping electrode **system** 168 contacts the tissue 128. Electrical signals are sensed by the mapping electrode **system** 168 and sent to a mapping **processor** where they are analyzed to determine if the pulmonary vein contains an arrhythmogenic origin for **atrial arrhythmia**.

If it is determined that the pulmonary vein contains an arrhythmogenic origin 130, the **ablation electrode system** 144 is positioned to ensure that it circumferentially engages the tissue around the pulmonary vein ostium 124. Energy is then applied to the ablation electrode **system** 144 to ablate the tissue around the ostium 124 to thereby form a circumferential **lesion** 132 which blocks electrical conduction from the arrhythmogenic origin 130 along the longitudinal axis into the left atrium. To ensure the formation of a continuous circumferential **lesion** 132, energy may be applied to the **ablation electrode system** 144 using a combination unipolar/bipolar **technique** and/or phasing **technique** such as those described in U.S. Patent Nos. 6,050,994, 6,059,778 and 6...  
...incorporated by reference.

With reference to FIG. 14, in another embodiment of the invention, a **catheter system** 200 includes a **catheter** shaft 202 having a radially expandable member 204 at its distal end.

In one configuration...in an array at the distal end of the balloon 204 form a mapping electrode **system** 212. The mapping electrodes 210 may comprise a metallic material deposited on the outer surface of the balloon using known **techniques**, such as but not limited to plasma depositing, sputter coating or chemical vapor deposition. An ablation electrode **system** 214 is positioned at the proximal end region 208 of the balloon 204. The ablation electrode **system** 214 may comprise one or more ablation electrodes 216 arranged to form a circumferential band...

...may comprise a metallic material deposited on the outer surface of the balloon 204.

The **catheter** shaft 202 includes a **lumen** that allows for deployment of the **catheter system** 200 over a **guide wire** 218. Alternatively, the **catheter system** 200 may be deployed through a guiding sheath.

With reference to FIG. 15, in operation, the distal end of the **catheter system** 200 is guided by a **guide wire** 218 to the interior of the pulmonary vein 126. Once properly positioned, the balloon 204 is inflated to a level sufficient to force contact between the mapping electrode **system** 212 and the circumferential wall of the vein 126. The mapping electrodes 210 sense pulmonary...

...throughout the circumference and depth of the pulmonary vein 126 and pass them to a mapping **processor** to determine if the pulmonary vein contains an arrhythmogenic origin for **atrial arrhythmia**.

If it is determined that the pulmonary vein contains an arrhythmogenic origin 130, the balloon is further inflated to force contact between the ablation electrode **system** 214 and the tissue around the pulmonary vein ostium 124. Energy is then applied to the ablation electrode **system** 214 to ablate the tissue around the ostium 124 to thereby form a circumferential **lesion** 132 which blocks electrical conduction from the arrhythmogenic origin 130 along the longitudinal axis of...

...vein 126 wall into the left atrium. To ensure the formation of a

continuous circumferential lesion 132, energy may be applied to the ablation electrode system 214 using a combination unipolar/bipolar technique and/or phasing technique such as that described in U.S. Patent Nos. 6,050,994, 6,059,778...the configuration thus described, a single balloon is used to deploy both the mapping electrode system and the ablation electrode system. In alternate configurations (not shown) of this embodiment, the catheter system employ multiple balloons. A first balloon deploys the mapping electrode system while a second balloon deploys the ablation electrode system.

With reference to FIG. 16, in another embodiment of the catheter system 240, the expandable member 242 comprises a matrix framework 244 or mesh positioned on and is secured to the balloon 246 through known adhesive bonding techniques and is expanded by inflation of the balloon. The construction of the framework 244 determines...

...end region 252 and the proximal-end region 254, respectively to define a mapping electrode system 256 and an ablation electrode system 258. The ablation electrodes 250 are positioned adjacent each other in a single row around...second metallic portion contains the ablation electrodes 250.

Conductive wires carried by the metallic portions serve as lead wires between the electrodes 248, 250 and the catheter shaft 262. The lead wires are carried within the wall of the expandable member 242 and into the catheter shaft 262. For a configuration deployed using a guidewire 264, the lead wires are carried by the wall of the catheter shaft 262 to the proximal end of the catheter. The metallic portions are separated by a non-metallic portion 260. In a preferred embodiment, the non-metallic portion is formed from...

#### Claim

I. A catheter system for use during electrophysiological procedures on biological tissue, said catheter system comprising:  
an outer catheter having a lumen therethrough and a distal-end region carrying a first electrode system; and  
an inner catheter sized to fit within the lumen and to slide therein, the inner catheter having a distal-end region carrying a second electrode system.

2 The catheter system of claim I wherein the first electrode system comprises a plurality of band electrodes positioned along the length of the distal-end region. 3 The catheter system of claim 1 wherein the second electrode system comprises a plurality of band electrodes positioned along the length of the distal-end region.

4 The catheter system of claim 1 wherein the outer catheter further comprises a tendon having a distal end attached to the distal-end region of the outer catheter and a proximal end exiting the proximal end of the outer catheter, wherein movement of the tendon along the length of the outer catheter causes the distal-end region of the outer catheter to curve. 5 The catheter system of claim I wherein the outer catheter is configured to have a preshaped curve at its distal-end region.

6 The catheter system of claim 5 wherein the preshaped curve is imparted by a shaped-memory stylet carried by the distal-end region of the outer catheter. 7 The catheter system of claim 5 wherein the

preshaped curve is generally circular.

8 The **catheter system** of claim 5 wherein the preshaped curve has a radius of curvature and the outer **catheter** further comprises a tendon having a distal end attached to the distal end of the outer **catheter** and a proximal end exiting the proximal end of the outer **catheter**, wherein movement of the tendon along the length of the outer **catheter** decreases the radius of curvature.

9 The **catheter system** of claim 1 wherein the inner **catheter** further comprises a tendon having a distal end attached to the distal-end region of the inner **catheter** and a proximal end exiting the proximal end of the inner **catheter**, wherein movement of the tendon along the length of the outer **catheter** causes the distal-end region of the inner **catheter** to curve.

10 The **catheter system** of claim 1 wherein the inner **catheter** is configured to have a preshaped curve at its distal-end region.

11 The **catheter system** of ...imparted by a shaped-memory stylet carried by the distal-end region of the inner **catheter**.

12 The **catheter system** of claim 10 wherein the preshaped curve is generally circular.

13 The **catheter system** of claim 10 wherein the preshaped curve has a radius of curvature and the inner **catheter** further comprises a tendon having a distal end attached to the distal end of the inner **catheter** and a proximal end exiting the proximal end of the inner **catheter**, wherein movement of the tendon along the length of the inner **catheter** decreases the radius of curvature.

14 The **catheter system** of claim 1 wherein the outer **catheter** comprises:  
an outer tubular member;  
an inner tubular member slidably disposed within the outer tubular member and  
defining the outer- **catheter lumen** ;  
a plurality of outwardly bendable segments secured at their distal ends to the distal-end bend outward. . The **catheter system** of claim 14 wherein the first electrode **system** comprises at least one electrode positioned on one of the bendable segments.

16 The **catheter system** of claim 14 wherein the first electrode **system** comprises a plurality of electrodes positioned on the bendable segments.

17 The **catheter system** of claim 1 further comprising:  
a generator adapted to provide energy to the first electrode **system** ;  
and  
a **processor** adapted to receive electrical signals from the second electrode **system**, the signals indicative of electrical activity in the tissue.

18 The **catheter system** of claim 1 further comprising:  
a generator adapted to provide energy to the second electrode **system** ;  
and a **processor** adapted to receive electrical signals from the first electrode **system**, the signals indicative of electrical activity in the tissue.

19 A **catheter system** for use during electrophysiological procedures

on biological

tissue, said **catheter system** comprising:

an outer **catheter** having tubular wall defining a lumen, the wall having an orifice, a distal-end region carrying a first electrode **system** and a proximal-end region; and an inner **catheter** sized to fit within the lumen and to slide therein and to fit through the orifice, the inner **catheter** having a distal-end region carrying a second electrode **system**.

20 The **catheter system** of claim 19 wherein the tubular member comprises a resiliently deformable junction section between the...

...orifice with the axis of the proximal-end region of the tubular wall.

21 The **catheter** of claim 20 wherein the normally bent form comprises an approximate 90 degree bend. . The **catheter system** of claim 20 wherein the outer **catheter** further comprises a tendon having a distal end attached ...region to deflect about the junction section relative to the proximal-end region.

23 The **catheter system** of claim 19 wherein the outer **catheter** comprises a shapememory stylet for imparting a preshaped curve to the distal-end region of the tubular wall.

24 The **catheter system** of claim 19 wherein the inner **catheter** comprises a shapememory stylet for imparting a preshaped curve to the distal-end region of the inner **catheter** .

25 The **catheter system** of claim 19 wherein:  
the outer **catheter** comprises a shape-memory stylet for imparting a generally circular curve to the distal-end...

...of the tubular wall, the curve lying substantially within a first plane; and  
the inner **catheter** comprises a shape-memory stylet for imparting a generally circular curve to the distal-end region of the inner **catheter** , the curve lying substantially within a second plane, the second plane being substantially parallel to the first plane.

26 The **catheter system** of claim 19 wherein the first electrode **system** comprises a plurality of band electrodes positioned along the length of the distal-end region.

27 The **catheter system** of claim 19 wherein the second electrode **system** comprises a plurality of band electrodes positioned along the length of the distal-end region.

28 The **catheter system** of claim 25 wherein the first electrode **system** and the second electrode **system** each comprise a plurality of band electrodes positioned along the length of the their respective distal-end region and the **catheter system** further comprises an alignment **system** adapted to align the curved distal-end region of the inner **catheter** with the curved distal-end region of the outer **catheter** such that the band electrodes of the respective **catheters** are aligned with each other. . The **catheter system** of claim 28 wherein the alignment **system** comprises a pair of markers, each visible under fluoroscopy, one marker carried on the proximal region of the inner **catheter** and the other marker carried on the proximal region of the outer **catheter** .

30 The **catheter system** of claim 28 wherein the alignment **system** comprises a groove along the outer surface of the proximal region of the inner **catheter** and a complementary protrusion along the inner surface of the outer **catheter** .

31 The **catheter system** of claim 28 wherein the alignment **system** comprises a protrusion along the outer surface of the proximal region of the inner **catheter** and a complementary groove along the inner surface of the outer **catheter** .

32 The **catheter system** of claim 19 further comprising:  
a generator adapted to provide energy to the first electrode **system** ;  
and  
a **processor** adapted to receive electrical signals from the second electrode **system** , the signals indicative of electrical activity in the tissue.

33 A **method** of performing an electrophysiological **procedure** on biological tissue within a biological site, said **method** comprising:  
positioning a first **catheter** within the biological site proximate the biological tissue, the first **catheter** having distal-end region carrying a first electrode **system** ; sensing electrical activity within the tissue through the first electrode **system** ; processing the electrical activity to identify the origin of an electrophysiological condition;

guiding a second **catheter** , via the first **catheter** , into the biological site, the second **catheter** having a distal-end region carrying a second electrode **system** ;

positioning the second **catheter** such that the second electrode **system** is adjacent the identified origin; and  
applying energy to the second electrode **system** to ablate the identified origin. . The **method** of claim 33 wherein the first **catheter** comprises a tubular wall defining a **lumen** and the step of guiding the second **catheter** comprises the step of sliding the second **catheter** through the **lumen** .

35 The **method** of claim 34 wherein the step of positioning the second **catheter** such that the second electrode **system** is adjacent the identified source comprises the steps of sliding the second **catheter** through the **lumen** until the second electrode **system** is substantially coincident with the first electrode **system** ; and repositioning the first **catheter** relative the second **catheter** to expose the second electrode **system** .

36 The **method** of claim 33 wherein the second **catheter** comprises a tubular wall defining a **lumen** and the step of guiding the second **catheter** comprises the step of sliding the second **catheter** over the first **catheter** .

37 The **method** of claim 36 wherein the step of guiding the second **catheter** further comprises the step of positioning the second **catheter** relative the first **catheter** such that the first **catheter** is within the **lumen** .

38 The **method** of claim 36 wherein the step of positioning the second **catheter** such that the second electrode **system** is adjacent the identified source comprises the step of sliding the second **catheter**

over the first **catheter** until the second electrode **system** is coincident with the first electrode **system** .

39 A **method** of performing an electrophysiological **procedure** on biological tissue proximate a pulmonary vein, said **method** comprising the steps of: positioning a first **catheter** near the ostium of the pulmonary vein, the first **catheter** having a distal-end region carrying a first electrode **system** ; guiding a second **catheter** , via the first **catheter** , into the pulmonary vein, the second **catheter** having a distal-end region carrying a second electrode **system** ; sensing electrical activity within the pulmonary-vein tissue through the first electrode **system** ; processing the electrical activity to confirm the existence of an abnormal electrophysiological condition originating within the pulmonary vein; upon confirmation, applying energy to the first electrode **system** to ablate the tissue near the ostium.

40 The **method** of claim 39 wherein the first **catheter** comprises a tubular wall defining a **lumen** and the step of guiding the second **catheter** comprises the step of sliding the second **catheter** through the lumen.

41 The **method** of claim 39 wherein the first **catheter** further comprises a resiliently deformable shape-memory stylet for imparting a generally circular curve to the distal-end region of the first **catheter** and the step of positioning the first **catheter** near the ostium of the pulmonary vein comprises the steps of straightening the distal-end region ...

...such that the curved portion of the region contacts the tissue defining the ostium.

42 The **method** of claim 41 wherein the step of straightening the distal-end region comprises positioning the first **catheter** over a **guide wire** leading to the heart and ...of allowing the distal-end region to assume its curved shape comprises positioning the **guide wire** and the distal-end region of the first **catheter** relative each other such that the **guide wire** is proximal the distal-end region of the first **catheter** .

43 The **method** of claim 41 wherein the step of straightening the distal-end region comprises positioning the first **catheter** within a guiding sheath leading to the heart and the step of allowing the distal **catheter** relative each other such that the distal-end region of the first **catheter** is beyond the distal end of the guiding sheath.

44 The **method** of claim 39 wherein the second **catheter** further comprises a resiliently deformable shape-memory stylet for imparting a generally circular curve to the distal-end region of the second **catheter** and the step of positioning the second **catheter** within the pulmonary vein comprises the steps of straightening the distal-end region to allow entry...vein such that the curved portion of the region contacts the tissue defining the vein **lumen** .

45 The **method** of claim 44 wherein the step of straightening the

distal-end region comprises the step of positioning the distal-end region within the tubular wall

46 The **method** of claim 45 wherein the first **catheter** comprises a tubular wall having a sidewall orifice and the step of allowing the distal-end region of the second **catheter** to assume its curved shape comprises the step of advancing the distal-end region through the orifice.

47 The **method** of claim 39 wherein the first **catheter** comprises an outer tubular member, an inner tubular member slidably disposed within the outer tubular member and defining a first- **catheter** lumen and a plurality of outwardly bendable segments secured at their distal ends to the first **catheter** near the ostium of the pulmonary vein comprises the step of moving the inner tubular...

...in the proximal direction until the segments contact the tissue defining the ostium.

48 The **method** of claim 47 wherein the first electrode **system** comprises at least one electrode positioned on one of the bendable segments and the step of moving the inner **tubes** comprises moving the inner **tube** until the at least one electrode contacts the tissue. . The **method** of claim 47 wherein the first electrode **system** comprises a plurality of electrodes positioned on the bendable segments and the step of moving the inner **tubes** comprises moving the inner **tube** until the electrodes contacts the tissue.

50 A **catheter system** for performing electrophysiological **procedures** on biological tissue, said **catheter system** comprising:  
a **catheter** sheath carrying a circumferentially expandable member at its distal end;  
a first electrode **system** positioned on the expandable member; and  
a second electrode **system** positioned on the expandable member, proximal the first electrode **system** .

51 The **catheter system** of claim 50 wherein the expandable member comprises a distal segment with a first expandable diameter, the first electrode **system** positioned at the distal segment and the second electrode **system** positioned at the proximal segment.

52 The **catheter system** of claim 51 wherein the first electrode **system** comprises a plurality of electrode elements arranged to form a circumferential band around the distal segment of the expandable member.

53 The **catheter system** of claim 51 wherein the second electrode **system** comprises a plurality of electrode elements arranged to form a circumferential band around the proximal segment of the expandable member.

54 The **catheter system** of claim 51 wherein the expandable member comprises a balloon and the first electrode **system** and the second electrode **system** are carried by the surface of the balloon.

55 The **catheter system** of claim 51 wherein the expandable member comprises an expandable framework. . The **catheter system** of claim 55 wherein the distal segment and proximal segment of the expandable framework comprise electrically conductive material.

57 The **catheter system** of claim 56 wherein the expandable framework further comprises a middle segment positioned between the distal segment

and the proximal segment and the middle segment comprises nonconductive material.

58 The **catheter system** of claim 51 wherein the expandable member further comprises a balloon surrounded by the framework and secured thereto.

59 The **catheter system** of claim 50 further comprising:  
a **processor** adapted to receive electrical signals from the first electrode **system**, the  
signals indicative of electrical activity in the tissue; and  
a generator adapted to provide energy to the second electrode **system**.

60 A **method** of performing an electrophysiological **procedure** on biological tissue proximate a pulmonary vein, said **method** comprising the steps of:  
positioning a circumferentially expandable member having a distal-end region and...tissue defining the ostium of the pulmonary vein, the expandable member having a first electrode **system** on the distal-end region and a second electrode **system** on the proximal-end region;  
expanding the circumferentially expandable member such that the first electrode **system** contacts the tissue defining the pulmonary vein and the second electrode **system** contacts the tissue defining the ostium;  
sensing electrical activity within the pulmonary-vein tissue through the first electrode **system**;  
processing the electrical activity to confirm the existence of an abnormal electrophysiological condition originating within the pulmonary vein; and upon confirmation, applying energy to the first electrode **system** to ablate the tissue near the ostium.



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TISSUE ABLATION DEVICE ASSEMBLY AND METHOD FOR ELECTRICALLY ISOLATING A  
PULMONARY VEIN OSTIUM FROM AN ATRIAL WALL

ENSEMBLE DE DISPOSITIF D'ABLATION TISSULAIRE ET PROCEDE D'ISOLATION  
ELECTRIQUE D'UN OSTIUM DE VEINE PULMONAIRE A PARTIR D'UNE PAROI ATRIALE

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Detailed Description  
Claims

Detailed Description

... of tissue along the atrial wall and which surrounds a vein ostium.  
Thereafter, the looped **ablation** element may be actuated to **ablate** the  
engaged tissue, such as for further illustration like a branding iron  
forming the predetermined pattern around the pulmonary vein ostium. In  
addition, other device or **method** variations may also be suitable  
substitutes according to one of ordinary skill.

Fig.'s 9A...

...it is used to form a circumferential conduction block adjunctively to  
the formation of long **linear lesions** in a lessinvasive 'maze'-type  
**procedure**, as introduced above for the treatment of multiwavelet  
reentrant type **fibrillation** along the left atrial wall.

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FIGURES  
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VERSION

More specifically, Fig. 9A diagrammatically shows a summary of steps for performing a "maze"-type **procedure** by forming circumferential conduction blocks that intersect with long **linear** conduction blocks formed between the pulmonary veins. As disclosed in U.S. Patent No. 5...

...entitled "Tissue Ablation Device and Method of Use", a box-like conduction block surrounding an **arrhythmogenic atrial** wall region bounded by the pulmonary veins may be created by forming long **linear lesions** 57, 58 and 59 between anchors in all pairs of adjacent pulmonary vein ostia, such...

...6) of Fig. 9A. However, it is further believed that, in some particular applications, such **linear lesions** may be made sufficiently narrow with respect to the surface area of the pulmonary vein...

...proarrhythmic pathways for abnormal conduction into and from the box, such as is shown between **linear lesions** 57 and 58 in Fig. 913.

I 0 Therefore, by forming ...9A, and as shown by use of circumferential ablation member 450 in Fig. 9C, the **linear lesions** 57 and 58 are thereby bridged and the gaps are closed.

In a further variation...

...913-C, Fig. 9D shows another circumferential ablation device assembly, which includes both circumferential and **linear** ablation elements 452 and 5 461, respectively. Circumferential ablation member 450 is shown to include...

...470 that is adjusted to a radially expanded position that is asymmetric to the underlying **catheter** shaft. **Linear** ablation member 460 extends along the elongate **catheter** body proximally from the circumferential ablation member 450. When expanded sufficiently to engage the pulmonary ...

...470 provides at least a portion of an anchor for a first end 462 of **linear** ablation member 460.

A shaped stylet 466 is shown in shadow in Fig. 9D within the elongate **catheter** body in the region of the second end 464 of the **linear** ablation member 460. Shaped stylet 466 is adapted to push the second end 464 into an adjacent pulmonary vein ostium such that the **linear** ablation member 460 is adapted to substantially contact the left atrial wall between the adjacent vein ostia to form the **linear ablation** according to the **method** of Fig. 9A. In addition to the use of shaped stylet 466, it is further...

...anchor may be used adjacent to second end 464, such as for example an intermediate **guidewire** tracking member adapted to track over a **guidewire** engaged within the pulmonary vein, as shown in Fig. 9E at intermediate **guidewire** tracking member 466' which is engaged over **guidewire** 467.

Moreover, the **method** shown schematically in Fig. 9A and also in various detail by reference to Fig.'s...

...specific sequence of steps for the purpose of illustration. According to this illustrative sequence, the **linear lesions** are formed first and then are connected thereafter with the circumferential conduction block. However, a circumferential conduction block may be formed prior to the formation of the **linear lesions** or conduction blocks, or in any other

combination or sub-combination of sequential steps, so long as the resulting combination of **lesions** allows for the circumferential block to intersect with and connect with the **linear lesions**. In addition, the circumferential conduction block which connects the **linear lesions** may also include a circumferential path of tissue which surrounds and **electrically** isolates the pulmonary vein ostium from the rest of the left posterior **atrial** wall, such as for example by considering the embodiments just shown and described by reference...

...the particular embodiments just shown and described by reference to Fig.'s 9A-E, other **methods** are also contemplated for combining circumferential and **linear** conduction blocks device assemblies and uses in order to perform a less-invasive "maze"-type **procedure**. For example, Fig. 9F shows one particular **lesion** pattern which results by combining a circumferential conduction block 57, formed according to the previous embodiments of Fig.'s EIA-C, with a pair of **linear lesions** which are formed according to the **method** illustrated by Fig. 9I3. In a further example shown in Fig. 9G, another **lesion** pattern is formed by combining the pair of **linear lesions** of Fig. 9B with a circumferential conduction block formed according to the embodiments which are previously illustrated above by I 0 reference to Fig.'s 9D-F. While the resulting **lesion** patterns of Fig.'s 9F and 9G differ slightly as regards the particular geometry and...

...wall tissue. When such circumferential conduction blocks are formed between adjacent pulmonary vein ostia, shorter **linear lesions** are therefore sufficient to bridge the circumferential **lesions** during the overall "maze"-type **procedure**.

5 To this end, the invention further contemplates one further variation for a less-invasive "maze"-type **procedure** (not shown) wherein multiple circumferential conduction blocks are formed in **atrial** wall tissue such that each pulmonary vein ostium is surrounded by and is electrically **isolated** with one circumferential conduction block. A series of four **linear lesions** may be formed between the various pairs of adjacent ostia and with just sufficient length...

...conduction block is thereby formed by the four circumferential conduction blocks and the four bridging **linear lesions**. A fifth **linear lesion** may be also formed between at least a portion of the box-like conduction block...

...along atrial wall tissue around the pulmonary vein ostia during a less invasive "maze"-type **procedure**. According to this further variation, the circumferential conduction block patterns formed around each of two ...

...vein ostia are shown in Fig. 9H to intersect, thereby alleviating the need for a **linear lesion** in order to form a conduction block between the ostia. Furthermore, the distances between the...

...to be positioned vertically between the inferior-superior pairs of adjacent ostia, and further shows **linear lesions** which are used to connect the right and left sided ostia of the superior and inferior pairs. In some instances these **linear lesions** will not be required to cure, treat or prevent a particular atrial **arrhythmia** condition. However, other combinations of these patterns are further contemplated, such as for ...between all adjacent pairs of ostia in order to form the entire "maze"-type left **atria** [ pattern. Fig. 10 diagrammatically shows a further method for using the circumferential **ablation** device assembly of the present invention

wherein electrical signals along the pulmonary vein are monitored...

...8) in Fig. 10, in order to confirm that the pulmonary vein chosen contains an **arrhythmogenic** origin for atrial **arrhythmia**. Failure to confirm an **arrhythmogenic** origin in the pulmonary vein, particularly in the case of a patient diagnosed with focal **arrhythmia**, may dictate the need to monitor signals in another pulmonary vein in order to direct...

...In addition, monitoring the preablation signals may be used to indicate the location of the **arrhythmogenic** origin of the atrial **arrhythmia**, which information helps determine the best location to form the conduction block. As such, the conduction block may be positioned to include and therefore **ablate** the actual focal origin of the arrhythmia, or may be positioned between the focus and the **atrium** in order to block aberrant conduction from the focal origin and into the **atrial** wall.

In addition or in the alternative to monitoring electrical conduction signals in the pulmonary vein prior to **ablation**, electrical signals along the pulmonary vein wall may also be monitored by the sensing element subsequent to circumferential ablation, according to step (9) of the **method** of Fig. 10. This monitoring **method** aids in testing the efficacy of the ablation in forming a complete conduction block against **arrhythmogenic** conduction. **Arrhythmogenic** firing from the identified focus will not be observed during signal monitoring along the pulmonary vein wall when taken below a continuous circumferential and transmural **lesion** formation, and thus would characterize a successful circumferential conduction block. In contrast, observation of such **arrhythmogenic** signals between the **lesion** and the atrial wall characterizes a functionally incomplete or discontinuous circumference (gaps) or depth (transmurality) which would potentially identify the need for a subsequent follow-up **procedure**, such as a second circumferential **lesioning procedure** in the ablation region.

A test electrode may also be used in a "post ablation" signal monitoring **method** according to step (10) of Fig.

10. In one particular embodiment not shown, the test electrode is positioned on the distal end portion of an elongate **catheter** body and is electrically coupled to a current source for firing a test signal into ...

...tissue surrounding the test electrode when it is placed distally or 'upstream' of the circumferential **lesion** in an attempt to simulate a focal **arrhythmia**. This test signal generally challenges the robustness of the circumferential **lesion** in preventing atrial **arrhythmia** from any such future physiologically generated aberrant activity along the suspect vein.

Further to the signal monitoring and test stimulus **methods** just described, such **methods** may be performed with a separate electrode or electrode pair located on the **catheter** distal end portion adjacent to the region of the circumferential ablation element, or may be...

...expandable member and ablation element structures that are adapted for use in such assemblies and **methods** are further provided as follows.

Notwithstanding their somewhat schematic detail, the circumferential ablation members shown...

...a fluid passageway (not shown in the Fig.'s) that extends proximally

- along the elongate **catheter** body and terminates proximally in a proximal fluid port that is adapted to couple to...
- ...is constructed of a relatively inelastic polymer such as a I O polyethylene ('PE'; preferably **linear** low density or high density or blends thereof), polyolefin copolymer ('POC'), polyethylene terephthalate ('PET'), polyimide...
  - ...order to facilitate introduction of the balloon into the desired ablation location via known percutaneous **catheterization techniques**. In this variation, one balloon size may not suitably engage all pulmonary vein walls for 15 performing the circumferential ablation **methods** of the present invention on all needy patients. Therefore, it is further contemplated that a kit of multiple ablation **catheters**, with each balloon working length having a unique predetermined expanded diameter, may be provided from...another aspect of the narrow equatorial band variation for the circumferential ablation element, the circumferential **lesion** formed may also be relatively narrow when compared to its own circumference, and may be...
  - ...element when expanded. In one arrangement which is believed to be suitable for ablating circumferential **lesions** in the pulmonary veins as conduction blocks, the band width  $w$  is less than 1...
  - ...further variation of a circumferential ablation element which is adapted to maintain a continuous circumferential **lesion** pattern over a range of expanded diameters and which includes electrode elements that form a...
  - ...elements 562, when the balloon is expanded, is adapted to form a substantially continuous circumferential **lesion** at a location where a pulmonary vein extends from an atrium when in intimal contact adjacent thereto, and is further adapted to form such a **lesion** over a range of band diameters as the working length is adjusted between a variety...
  - ...LA is at an acute angle relative to the longitudinal axis  $L_a$  of the elongate **catheter** body and expandable member 560. At least one of the ends 563, 564 along the...
  - ...ablation element design which is believed to be highly useful in performing the I O **methods** according to the present invention is shown in Fig. 13 to include a circumferential ablation...
  - ...620 positioned coaxially over an inner tubular member 621 which is included in a coaxial **catheter** design as would be apparent to one of ordinary skill. Such a radiopaque marker may...a circumferential path of tissue along a pulmonary vein wall which circumscribes the pulmonary vein **lumen** when the looped member 710 is delivered from the delivery sheath 750 when the delivery sheath is positioned within the vein **lumen** parallel to its longitudinal axis. An ablation electrode 714 is also shown in Fig. 15...s 16-31 below are believed to provide assemblies that are particularly well adapted for **ablating** a circumferential region of tissue along the posterior left **atrial** wall that surrounds a pulmonary vein ostium and isolates the surrounded tissue including the pulmonary...
  - ...rest of the left atrium in order to prevent atrial fibrillation.

According to the circumferential **ablation** device assembly 1600 shown in Fig.'s 16A-C, a plurality of electrodes 1630 are spaced along elongated member 1625, which is disposed on the distal end portion of **catheter** 5 body 1610. Elongated member 1625 is adjustable between a first shape

(shown in Fig. 16A), which substantially extends along the longitudinal axis L of **catheter** body 1610, to a second shape (Fig. 16B), which has a looped geometry about a...

...The first shape is adapted for delivery through a delivery sheath and into the left **atrium**. The second shape is adapted to position the ablation elements about a circumference in order...

...for ablating a circumferential region of tissue where a pulmonary vein extends from a left **atrium**.  
More specifically, an actuating assembly incorporating pull wire 1667 is used to adjust the elongated...

...further through port 1618 where it is slideably engaged within a passageway (not shown) along **catheter** body 1610, terminating along the proximal end portion of **catheter** body 1610, where it may be manipulated. Because the distal end 1626 of elongated member 1625 is also secured to tip 1619, pulling pull wire 1627 relative to **catheter** body 1610 longitudinally collapses distal end 1626 toward proximal end 1624 along pull wire 1627 and thereby deflects elongated member 1625 radially outwardly from the **catheter** assembly. By pre-forming a bias onto elongated member, the elongated member 1625 forms a loop along a plane that is orthogonal to the longitudinal axis of the **catheter** body 1610, as shown in Fig.'s 16B-C.

Moreover, the assembly 1600 is further shown to be adapted to track over a **guidewire** 1602 via a **guidewire** lumen 1615 that is shown in Fig.'s 16A-C to extend along elongated member 1625 and further proximally along **catheter** body 1610. As such, elongated member 1625 is preferably positioned over a sufficiently flexible portion of the **guidewire** in order to form the **looped** shape as just described. Moreover, it is further contemplated that distal and proximal **guidewire** tracking members or bores (not shown) may be provided on distal tip 1619 and **catheter** body 1610, respectively, such that the **guidewire** 1602 may also extend along the outside of elongated member 1625 and pull wire 1627, such that the elongate member's shape when deflected is not affected by **guidewire** 1602.

Further to this dual tracking member embodiment, a stop (not shown) may be provided on **guidewire** 1602 distally of distal tip 1619 such that pull wire 1627 is...

...proximal and distal ends 1624, 1626 of elongated member 1625 are longitudinally collapsed together along **guidewire** 1602 to provide the desired deflection for elongated member 1625.

Circumferential ablation device assembly 1700...

...pushing member (not shown) that is slideably engaged within a passageway 1717 extending proximally along **catheter** body 1710. In addition, a distal member 1712 extends distally from **catheter** body 1710 and beyond the circumferential ablation member 1720 in order to track over **guidewire** 1702 slideably engaged in **guidewire** passageway 1715 and anchor distally within the pulmonary vein while circumferential ablation member 1720 engages...

...of tissue where the vein extends from the atrial wall, and in particular along the **atrial** wall and surrounding the vein ostium. A balloon 1716 is also shown in Fig. 17...

...1724 of elongate member 1725 in order to facilitate formation of complete and continuous circumferential **lesions**. It is further contemplated that the distal end portion of elongate member 1725, such as ...shape during use. According to one aspect of the Fig. 17 embodiment as just described, **catheter** 1701 may be secured in position, such as by inflating a balloon 1716 within a...

...while circumferential ablation member 1720 is advanced distally and adjusted as desired relative to the **catheter** in order to form the desired **lesion**.

Circumferential ablation device assembly 1800 shown in Fig. 18 provides a plurality of individual ablation...

...for advancing against tissue for ablation, such as against a posterior left atrial wall to **ablate** around a pulmonary vein ostium. One such shape incorporating a forward-looking face of the...

...wall 1911 extending at least in part along the distal end portion of **catheter** body 1910. A distal end 1913 of tubular wall 1911 is secured to an inner...

...of the spline members and within a passageway extending to the proximal end portion of **catheter** body 1910. By advancing tubular wall 1911 distally with respect to inner member 1912, distal...

...be arranged on other regions of the splines to allow for the formation of circumferential **lesions** of different circumferential regions of tissue. In one alternative, for example, an individual ablation element ...

...the spline 1925 in the second position, thereby forming a circumferential ablation element adapted to **ablate** tissue confronted by the splines as the assembly is advanced distally, such as for example against a posterior left atrial wall to **ablate** tissue surrounding a pulmonary vein.

Other alternative spline configurations to that just described for Fig... extend distally from a delivery passageway 2017 (shown in Fig.'s 20B & 20C) of a **catheter** body 2010 with a shape that extends radially outwardly from the longitudinal axis of **catheter** body 2010. Ablation elements 2030 are thereby positioned by spline members 2025 along a...

...are positioned in a circumferential array (Fig.'s 20B & 20C). Inner member 2012 includes a **guidewire** passageway 2015 for slideably engaging and tracking over a **guidewire**. A balloon 2016, or other expandable member, is shown in shadow in Fig. 20A on...

...2012 within a pulmonary vein after inner member 2012 is tracked into the vein over **guidewire**. As such, Fig.'s 20B-C show inner member 2012 to also include a second passageway as an inflation **lumen** 2014 in order to I O inflate such a balloon 2016.

The configuration shown in Fig.'s 20A-B represents a second position for the **ablation** elements 2030.

However, in a different mode of operation during delivery to the left **atrium** (not shown), the distal end portions 2026 of spline members 2025 are radially confined in...

...and housed within delivery passageway 2017 in the first position during

delivery to the left atrium .

Fig. 20B further shows alternative '+' and '-' symbols associated with each of the **ablation** elements 2030, one mode of this embodiment wherein ablation elements 2030 provide an assembly of...

...electrodes, thereby ablating that tissue. By ablating tissue between all such poled pairs, a circumferential **lesion** may be formed according to the invention. Further, such bipolar ablation about the circumferential region...

...may be gated for actuation only during discrete periods of time during an overall **ablation procedure** . For example, by actuating all at once, current flowing through any given positively poled electrode...

...order to maintain the requisite spacing between the individual elements so that a continuous circumferential **lesion** may be formed along circumferential regions of tissue with greater radii.

The distal end portions...

...s 20A or 20C. This illustrates that one shape may be preferred for different specific **lesions** to be formed. More specifically, the shapes shown in Fig.'s 20A and 21C may...

...left atrial wall in order to ablate a lesion surrounding a pulmonary vein ostium.

Circumferential **ablation** device assembly 2200 shown in Fig. 22A illustrates a further aspect of the invention wherein...

...2232, 2234 coupled to a supporting spline member 2225 which is adapted to adjust the **ablation** element 2230 from first to second positions for delivery into the atrium and circumferential **ablation** , respectively, in a similar manner as previously described above. While this design is believed to...

...monopolar fashion. Moreover, it is further believed that providing these ablation elements in a substantially **linear** , non-preshaped structure, they would tend to string **linearly** between their ends between the spline members, yielding a pattern for example such as is shown in Fig.

22B. Such pattern with substantially flat, **linear lesion** portions however may be limited in that spline members adjusted radially outward to radius R...

...members extending between spline members, such as is shown in Fig.'s 24A-B below.

**Lines** 23-23 shown in Fig. 22A are provided to illustrate that the various transverse cross-sectional views shown in Fig.'s 23A-C show **catheter** body or shaft structures that may be suitable for use according to the Fig. 22A...this assembly is bonded into a unitary construction along the proximal aspect of the corresponding **catheter** , such as by soldering the splines and spacers all together, which may be done for...

...aspect of this splineispace assembly are positioned within a coaxial space between outer and inner **tubing** of the elongate **catheter** body of the overall **catheter** assembly, such as between outer **tubing** 231 1 and inner **tubing** 231 2 shown in Fig. 23B and 23C. The outer **tubing** 221 1 may have a diameter of about 0.1 20 inches. Further, the coaxial...



...taken of such an assembly as that shown in Fig. 23A, although taken along the **catheter** distally beyond where the spacers terminate, and further shows that the coaxial space within which the assembly may be formed may surround an inner **catheter** shaft 2312 having multiple **lumens**, such as for example **lumens** for engaging a **guidewire**, inflating a distal balloon, actuating the corresponding ablation elements, etc. The inner **catheter** shaft 2312 may have a diameter of about 0.042 inches.

5 Fig. 23C also...

...embodiment wherein hypotube members are used to form spline members 2325' and provide an internal **lumen** 2326 that extend along spline members 2325'. These **lumens** 2326 may be used for example to deliver coupling members such as wires to the...

...supporting spline member, as shown in Fig. 24A, and is delivered to and from the **atrium** in a radially collapsed condition with the circumferential ablation member 2420 folded into a desired 'convoluted' shape and the **ablation** elements 2420 in first positions which are adapted for delivery in and out of a...into and from the left atrium, such as through delivery sheath 2410. This position for **ablation** elements 2430 results from adjusting spline members 2425 to a relatively radially collapsed condition, such...

...various electrical conductors or wires (not shown) are also to be included in the overall **catheter** assembly which electrically couple to and extend from each electrode and extend proximally from ablation member 2420 and along delivery sheath 2410 and/or **catheter** body 2411 to a proximal electrical coupler for coupling to an electrical current source ...

...be tubular such as hypotubes as elsewhere herein described, or via other communicating members or **tubing** extending between the positioned circumferential ablation element and the associated delivery **catheter** assembly. Furthermore, such a fluid coupling aspect of this embodiment further includes a proximal coupler...

...leg 2441 forming a first bore 2442 that receives in a fluid tight seal fluid **tubing** 2429 which coaxially surrounds spline member 2425. First leg 2441 terminates in fluid communication with...

...a fluid tight seals, terminal ends of porous members 2433, 2437, also respectively. Accordingly, fluid **tubing** 2429 is provided in fluid communication with the interior spaces 2434, 2438 of porous membranes 2433, 2437, respectively, via coupler 2440.

As shown in further detail in Fig. 24F, fluid **tubing** 2429 and spline member 2425 couple with **catheter** body 2410 through port 2418 and extend proximally through body 2410 through passageway 2417 and...

...respective couplers (not shown) for actuating the position for spline member 2425 and pressurizing fluid **tubing** 2429 with fluid. It is to be appreciated that such fluid may be for example...as illustrated with reference to Fig. 24A. This assembly is further collapsible through a delivery **catheter** 2610, as shown in Fig. 2613, in which configuration the circumferential ablation element 2635 may...

...some instances the mechanical action of retracting spline members within the corresponding delivery sheath or **catheter** may cause the folds to 'groom' into the configuration shown in Fig. 2413, since the...

...Fig.'s 26A-C is also believed to be beneficial for adapting the desired circumferential **ablation** element to ablate regions of tissue against the posterior left **atrial** wall and surrounding a pulmonary vein. More specifically, the side-by-side leg configurations bordered...

...of the distal wall 2860. As shown in greater detail in Fig. 27C, a fluid **tubing** 2729 is positioned between proximal and distal walls 2750, 2760 and terminates along unsealed circumferential region 2745 such that this void space communicates externally of housing 2740 only through fluid **tubing** 2729 and the pores along the porous portion of distal wall 2760 along that circumference. The same fluid coupling relationship is also illustrated in Fig. 28A & B. Fluid **tubing** 2729 and spline members 2725 couple proximally to various **lumens** or passageways (not shown) provided by delivery member 2710, as shown in part in Fig...

...material may be used in order to ensure a fluid tight seal around the fluid **tubing** 2729 and spline members 2725 and between the housing's respectively sealed walls, as shown...housing 2740 to a folded position that is adapted for delivery to and from the **atrium** for ablation (not shown). Once in the left **atrium**, spline members 2725 are advanced distally from the delivery sheath in the radially extended condition...

...allows for the radial adjustment of a housing 2840 by manipulation of cooperating portions of **catheter** body 2810 and without the need for withdrawal or advancement of a separate, confining delivery...

...for example, may be used for coupling the circumferential ablation member components to the corresponding **catheter**, as shown at tip housing 2812 in Fig. 28B. With reference to Fig.'s 28C...

...are shown, which include a circumferential ablation member located along a distal end portion of **catheter** body and includes a housing that forms a porous distal wall that covers the distal...

...a plurality of spline members.

In one embodiment, the distal tip of the elongate or **catheter** body may include an anchor (e.g., inflatable balloon), and/or a distal port of for a **guidewire**. Each of spline members includes: a proximal end portion that is secured to outer member of **catheter** body; a distal end portion that is secured to an inner member extending from within...

...member 2920. As in previous embodiments, the inner member 2912 is adapted to track over **guidewire** 2902. The distal end portions 2926 of spline members 2925 are shown in Fig. 29B...porous wall aspects of such embodiments may be constructed according to several known structures and **methods**. Porous fluoropolymers such as porous polytetrafluoroethylene (PTFE), and in particular the expanded variety (e-PTFE...

...wherein the corresponding housing including a porous region may be substantially tubular along the respective **catheter** assembly. Further to this aspect, it is further contemplated that such housings such as housing 3040 shown in Fig.'s 30A-D may be constructed of a contiguous elastomeric **tube** which has been made porous along only the ablative circumferential surface of the distal wall...

...tissue. The present circumferential ablation device has particular utility in connection with forming a circumferential **lesion** within or about a pulmonary vein ostium or within the vein itself in order to...

...to a large amount of current. For example, a collimated ultrasonic transducer can form a **lesion**, which has about a 1.5 mm width, about a 2.5 mm diameter **lumen**, such as a pulmonary vein and of a sufficient depth to form an effective conductive block. It is believed that an effective conductive block can be formed by producing a **lesion** within the tissue that is transmural or substantially transmural.

Depending upon the patient as well as the location within the pulmonary vein ostium, the **lesion** may have a depth of about 1 to 10 mm. It has been observed that the collimated ultrasonic transducer can be powered to provide a **lesion** having these parameters so as to form an effective conductive block between the pulmonary vein and the posterior wall of the left **atrium**.

With specific reference now to the embodiment illustrated in Fig.'s 31A through 31D, a circumferential **ablation** device assembly 800 includes an elongate **catheter** body 802 with proximal and distal end portions 810, 812, an expandable balloon 820 located along the distal end portion 812 of elongate **catheter** body 802, and a circumferential ultrasound transducer 830 which forms a circumferential ablation member that...

...to the expandable balloon 820. In more detail, Fig.'s 31A-C variously show elongate **catheter** body 802 to include **guidewire lumen** 804, inflation lumen 806, and electrical lead lumen 808. The ablation device, however, can be of a self-steering type rather than an over-the-wire type device.

Each **lumen** extends between a proximal port (not shown) and a respective distal port, which distal ports are shown as distal **guidewire** port B05 for **guidewire** lumen 804, distal inflation port 807 for inflation **lumen** 806, and distal lead port 809 for electrical lead **lumen** 808. Although the **guidewire**, inflation and electrical lead **lumens** are generally arranged in a side-by-side relationship, the elongate **catheter** body 802 can be constructed with one or more of these **lumens** arranged in a coaxial relationship, or in any of a wide variety of configurations that...

...be readily apparent to one of ordinary skill in the art.

In addition, the elongate **catheter** body B02 is also shown in Fig.'s 31 A and 31 C to include...

...formed by the expandable balloon 820, and distally beyond expandable balloon 820 where the elongate **catheter** body terminates in a distal tip. The inner member 803 forms the distal region for the **guidewire lumen** 804 beyond the inflation and lead ports, and also provides a support member for the...described in more detail below.

One more detailed construction for the components of the elongate **catheter** body 802 that is believed to be suitable for use in transeptal left **atrial ablation procedures** is as follows. The elongate **catheter** body 802 itself may have an outer diameter provided within the range of from about...

...10 French, and more preferable from about 7 French to about 9 French. The **guidewire** lumen preferably is adapted to slideably receive **guidewires** ranging from about 0.010 inch to about 0.038 inch in diameter, and preferably is adapted for use with **guidewires** ranging from about 0.018 inch to about 0.035 inch in diameter. Where a 0.035 inch **guidewire** is to be used, the **guidewire** lumen preferably has an inner diameter of 0.040 inch to about 0.042 inch...

...times, although may vary based upon the viscosity of inflation medium used, length of the **lumen**, and other dynamic factors relating to fluid flow and pressure.

In addition to providing the requisite lumens and support members for the ultrasound transducer assembly, the elongate **catheter** body 802 of the present embodiment must also be adapted to be introduced into the...

...balloon and transducer may be placed within the pulmonary vein ostium in a percutaneous transluminal **procedure**, and even more preferably in a transeptal **procedure** as otherwise herein provided. Therefore, the distal end portion 812 is preferably flexible and adapted to track over and along a **guidewire** seated within the targeted pulmonary vein. In one further more detailed construction which is believed...

...For example, while the Fig. 31 A variation is shown as an 'over-the-wire' **catheter** construction, other **guidewire** tracking designs may be suitable substitutes, such as, for example, **catheter** devices which are known as 'rapid exchange' or 'monorail' variations wherein the **guidewire** is only housed coaxially within a **lumen** of the **catheter** in the distal regions of the **catheter**. In another example, a deflectable tip design may also be a suitable substitute and which...

...the transducer assembly into the desired location for ablation. Further to this latter variation, the **guidewire** lumen and **guidewire** of the Fig. 31 A variation may be replaced with a 'pullwire' lumen and associated fixed pullwire which is adapted to deflect the **catheter** tip by applying tension along varied 0 stiffness transitions along the **catheter**'s length. Still further to this pullwire variation, acceptable pullwires may have a diameter within...

...5 proximal and distal adaptations B24, 826. The proximal adaption 824 is sealed over elongate **catheter** body 802 proximally of the distal inflation and the electrical lead ports 807, 809, and...

...This interior chamber is fluidly coupled to a pressurizeable fluid source (not shown) via inflation **lumen** 806. In addition to the inflation **lumen** 806, electrical lead **lumen** 808 also communicates with the interior chamber of expandable balloon 820 so that the ultrasound...

...the material elongates upon application of pressure and takes on the shape of the body **lumen** or space when fully inflated. Suitable balloon materials include elastomers, such as, for example, but...more detailed construction which is believed to be suitable for use in most conduction block **procedures** in the region of the pulmonary veins, the balloon is adapted to expand under a...

...of segments. For instance, the transducer applicator 830 can be formed by a plurality of **tube** sectors that 5 together form an annular shape. The **tube** sectors can also be of sufficient arc lengths so as when joined together, the sector...

...5 to 10 mm. A transducer accordingly sized is believed to form a -5 1 **lesion** of a width sufficient to ensure the integrity of the formed conductive block without undue...

...2 mm generates acoustic power levels approaching 20 Watts per centimeter radiator or greater within **myocardial** or vascular tissue, which is believed to be sufficient for **ablation** of tissue engaged by the outer balloon for up to about 2 cm outer diameter...Fig.'s 31A-D further show

leads 836, 837 as separate wires within electrical lead **lumen** 808, in which configuration the leads must be well insulated when in close contact. Other configurations for leads 836, 837 are therefore contemplated. For example, a **coaxial cable** may provide one cable for both leads which is well insulated as to inductance interference. Or, the leads may be communicated toward the distal end portion 812 of the elongate **catheter** body through different **lumens** that are separated by the **catheter** body.

The transducer also can be sectored by **scoring** or notching the outer transducer electrode 833 and part of the central layer B32 along **lines** parallel to the longitudinal axis L of the transducer 830, as illustrated in Fig. 31E...

...around the transducer 830, as well as can vary the degree of heating (i.e., **lesion** control) in the angular dimension.

The ultrasound transducer just described is combined with the overall...

...U.S. Patent No. 5,606,974 to Castellano issued March 4, 1997, and entitled '**Catheter** Having Ultrasonic Device.' More detailed examples of the alternative transducer support structures just described are...

...U.S. Patent No. 5,620,479 to Diederich, issued April 15, 1997, and entitled '**Method** and Apparatus for Thermal Therapy of Tumors.'

In the illustrated embodiment, at least one stand...

...between the splines, thereby minimizing dampening affects from the coupling of the transducer to the **catheter**. The tubular member that forms a stand-off such as stand-off region 838 in the Fig. 31C embodiment may also provide its inner bore as the **guidewire lumen** in the region of the ultrasound transducer, in the alternative to providing a separate stand...

...member, such as according to the Fig. 31C embodiment.

In a further mode, the elongate **catheter** body 802 can also include additional **lumens** which lie either side by side to or coaxial with the **guidewire lumen** 804 and which terminate at ports located within the space between the inner member 803...

...stand-off 838 between the inner member 803 and the transducer 830 via these additional **lumens**. By way of example, carbon dioxide gas, circulated at a rate of 5 liters per...

...the interior of the balloon 820.

Again, any of a variety of coatings, sheaths, sealants, **tubing** and the like may be suitable for this purpose, such as I O those described...and the inner member 803 at these locations.

An ultra thin-walled polyester heat shrink **tubing** 844 or the like then seals the epoxy coated transducer.

Alternatively, the epoxy covered transducer...

...off region 838 can be instead inserted into a tight thin wall rubber or plastic **tubing** made from a material such as TeflonO, polyethylene, polyurethane, silastic or the like. The **tubing** desirably has a thickness of 0.0005 to 0.003 inches.

When assembling the ablation device assembly, additional epoxy is injected into the **tubing** after the **tubing** is placed over the epoxy coated transducer 830. As the **tube** shrinks, excess epoxy flows out and a thin layer of epoxy remains between the transducer and the heat shrink **tubing** 844. These layers 842, 844 protect the transducer surface, help acoustically match the transducer 830...

...air backing.

Although not illustrated in Fig. 31A in order to simplify the drawing, the **tubing** 844 extends beyond the ends of transducer 830 and surrounds a portion of the inner...

...830. A filler (not shown) can also be used to support the ends of the **tubing** 844. Suitable fillers include flexible materials such as, for example, but without limitation, epoxy, Teflon...to this arrangement may be preventative of thrombus formation that might otherwise occur at a **lesion** sight, particularly in the left atrium.

The ultrasound transducer described in various levels of detail...

...desired location for ablating the conductive block. However, it is further contemplated that the elongate **catheter** body 802 may include an additional radiopaque marker or markers (not shown) to identify the...

...similar to that described in connection with the embodiment of Fig. 13.

The present circumferential **ablation** device is introduced into a pulmonary vein of the left **atrium** in a manner similar to that described above. Once properly positioned within the pulmonary vein or vein ostium, the pressurized fluid source inflates the balloon 820 to engage the **lumenal** surface of the pulmonary vein ostium. Once properly positioned, the ultrasonic driver 840 is energized...

...at 20 acoustical watts at an operating frequency of 7 MHz, that a sufficiently sized **lesion** can be formed circumferentially about the pulmonary vein ostium in a relatively short period of...

...is also contemplated that the control level of energy can be delivered, then tested for **lesion** formation with a test stimulus in the pulmonary vein, either from an electrode provided at the tip area of the ultrasonic **catheter** or on a separate device such as a **guidewire** through the ultrasonic **catheter**. Therefore, the **procedure** may involve ablation at a first energy level in time, then check for the effective conductive block provided by the resulting **lesion**, and then subsequent ablations and testing until a complete conductive block is formed. In the...

...balloon outer surface. Monitoring temperature at this location provides indicia for the progression of the **lesion**. This feedback feature may be used in addition to or in the alternative to the multi-step **procedure** described above.

Fig.'s 32A-C show various alternative embodiments of the present invention for...

...in Fig. 32A is also concentrically positioned relative to the longitudinal axis of the elongate **catheter** body 802. It is understood, however, that the balloon can be asymmetrically positioned on the elongate **catheter** body, and that the ablation device can include more than one balloon.

Fig. 32B shows...

...the device shown in Fig. 32C is believed to be suited to form a similar **lesion** to that shown at circumferential **lesion** 850 in Fig. 32D. Circumferential **lesion** 850 **electrically** isolates the respective pulmonary vein 852 from a substantial portion of the left **atrial** wall. The device shown in Fig. 32C is also believed to be suited to form an elongate **lesion** which extends along a substantial portion of the pulmonary vein ostium 854, e.g., between the proximal edge of the illustrated **lesion** 850 and the dashed **line** 856 which schematically marks a distal edge of such an exemplary elongate **lesion** 850.

As mentioned above, the transducer 830 can be formed of an array of multiple...can also include additional mechanisms to control the depth of heating. For instance, the elongate **catheter** body 802 can include an additional lumen that is arranged on the body so as to circulate the inflation fluid through a closed **system**. A heat exchanger can remove heat from the inflation fluid and the flow rate through the closed **system** can be controlled to regulate the temperature of the inflation fluid. The cooled inflation fluid...

...use of this feature and the temperature of the inflation fluid can be varied from **procedure** to **procedure**, as well as during a particular **procedure**, in order to tailor the degree of ablation to a given application or patient.

The...

...transducer 830 may be mounted on a torquable member that is movably engaged within a **lumen** that is formed by the elongate **catheter** body 802.

Another aspect of the balloon-transducer relationship of the present embodiment is illustrated...

...balloon coupling level such that a third order of control is provided for the tissue **lesion** pattern (the first order of control is the transducer properties affecting signal emission, such as length, width, shape of the transducer crystal; the second order of control for tissue **lesion** pattern is the balloon shape, per above by reference to Fig.'s 32A-C).

This third order of control for the tissue **lesion** pattern can be understood more particularly with reference to Fig. 33A, which shows balloon 820...

...830 may be required to be longer than the length which is desired for the **lesion** to be formed. Many **procedures** intending to form conduction blocks in the left atrium or pulmonary veins, such as, for example, less-invasive "maze"-type **procedures**, require only enough **lesion** width to create a functional electrical block and ...addition, limiting the amount of damage formed along an atria[ wall, even in a controlled **ablation procedure**, pervades as a general concern. However, a transducer that is necessary to form that block...

...desirable for other reasons, may require a length which is much longer and may create **lesions** which are much wider than is functionally required for the block. A "narrow pass" filter...

...sonically coupled to the transducer via the ultrasound signal. It is

believed that some ablation **methods** may benefit from combining ultrasound thermal conduction modes of ablation in a targeted circumferential band of...

...180 degree exposure).

The transducer can also have a planar shape. By rotating the elongate **catheter** body 802, the transducer B30 can be swept through 360 degrees in order to form...

...to a torquable member 803 within the balloon 820. The transducer 830 is formed by **curvilinear** section and is mounted on the inner member 803 with its concave surface facing in...

...pattern. By sweeping the transducer through 360 degrees of rotation, as described above, a circumferential **lesion** can be formed while using less power than would be required with a planar or...

...and described by reference to Fig.'s 31A-34B. These additional embodiments particularly adapt such ultrasound **ablation** members for use in ablating along a funneling, tapered pulmonary vein ostium or along a posterior left **atrial** wall tissue and surrounding the pulmonary vein's ostium.

Fig. 35A schematically illustrates formation of a **lesion** through a forward or distal facing wall of a distally 5 tapered balloon 3525 to form a **lesion** surrounding a pulmonary vein ostium, such as previously described above for circumferential **ablation** along a posterior left atrial wall surrounding a vessel ostium, or otherwise along the ostium.

As shown in Fig. 35A, the ultrasonic circumferential **ablation** device assembly 3501 may be adapted to track over a guide wire 3502 and into a pulmonary vein. The **lesion** 3560 surrounding a pulmonary vein ostium 3555 to which this embodiment is adapted to form is representative of those **lesions** which the other embodiments in Fig.'s 16A-30 are also adapted to form. More...other embodiments of the present invention.

Fig. 40 shows a further embodiment of an ultrasound **ablation** device for making circumferential lesions in the posterior wall of the left atrium around pulmonary vein(s). A circumferential **ablation** pattern perpendicular to the **catheter** shaft and ultrasound transducer 4030 is generated by deflecting the ultrasound energy using a surface...

...by reference to Fig.'s 31A-34B may be used according to several different particular **methods** such as those **methods** otherwise set forth throughout this disclosure. For example, any of the ultrasound transducer embodiments may be used to form a conduction block in order to prevent or treat focal **arrhythmia** arising from a specific pulmonary vein, or may alternatively or additionally be used for joining adjacent **linear lesions** in a less-invasive 'maze'-type **procedure**.

As discussed above, the embodiments described herein are believed to be particularly useful in **catheter** assemblies which are specifically adapted for **ablating** tissue along a region where a pulmonary vein extends from a left atrium in the treatment of **atrial fibrillation**. Therefore, the assemblies and **methods** of the present invention are also contemplated for use in combination with, or where appropriate...

...and embodiments shown and described in the following U.S. Patents that also address circumferential **ablation** at a location where a pulmonary vein extends from an atrium: U.S. Patent No. 6,024,740 for



"CIRCUMFERENTIAL **ABLATION** DEVICE ASSEMBLY' to Michael D. Lesh et al, filed July 8, 1997 and issued February 15, 2000; and U.S. Patent No. 6,012,457 for 'DEVICE AND **METHOD** FOR FORMING A CIRCUMFERENTIAL CONDUCTION BLOCK IN A PULMONARY VEIN' to Michael D. Lesh, filed...

...ablation device assembly according to the present invention may be used in combination with other **linear** ablation assemblies and **methods**, and various related components or steps of such assemblies or **methods**, respectively, in order to form a circumferential conduction block adjunctively to the formation of long **linear** lesions, such as in a less-invasive "maze"-type **procedure**. Examples of such assemblies and **methods** related to **linear** lesion formation and which are contemplated in combination with the presently disclosed embodiments ... Patent No. 5,971,983, issued on October 26, 1999, entitled 'TISSUE ABLATION DEVICE AND **METHOD** OF USE' filed by Michael Lesh, M.D. on May 9, 1997.

While a number of variations of the invention have been shown and described in detail, other modifications and **methods** of use contemplated within the scope of this invention will be readily apparent to those...

...fall within the scope of the invention. For example, the embodiments variously shown to be '**guidewire**' tracking variations for delivery into a left atrium and around or within a pulmonary vein may be modified to instead incorporate a deflectable/steerable tip instead of **guidewire** tracking and are also contemplated.

Moreover, all assemblies described are believed useful when modified to ...

...treating other conditions, wherein aberrant electrical conduction may be implicated, such as for example, heart **flutter**. Indeed, other conditions wherein **catheter**-based, directed tissue ablation may be indicated, such as for example, in the ablation of fallopian **tubé** cysts. Accordingly, it should be understood that various applications, modifications and substitutions may be made...

#### Claim

1. A tissue ablation system for treating atrial arrhythmia by **ablating** a circumferential region of tissue at a location where a pulmonary vein extends from an **atrium**, comprising:  
a circumferential **ablation** member with a circumferential support member that is adjustable between a first position which is adapted to be delivered through a delivery sheath into the **atrium** and a second position having a substantially circumferentially looped shape, an **ablation** element located substantially along the circumferential support member and that is adapted to ablatively couple...

...the first and second positions when the circumferential support member is substantially unconfined within the **atrium**; and  
a delivery assembly cooperating with the circumferential **ablation** member and which is adapted to at least in-part deliver the circumferential ablation member...

...support member is 1.5 adjusted to the second position at the location.

2 The **system** of claim 1, wherein the delivery assembly comprises a delivery member with a proximal end...

...second position the elongate body is adjusted to the substantially

circumferentially looped shape.

3 The **system** of claim 2, wherein the delivery member has a passageway extending between a distal port...

...at least in part the substantially looped shape between the longitudinally collapsed ends.

4 The **system** of claim 3, wherein the intermediate region is constructed with a predisposed bias toward the substantially looped geometry.

5 The **system** of claim 3, further comprising at least one indicator which indicates when the circumferential ablation member is in the second position.

6 The **system** of claim 5, wherein said at least one indicator comprises a first radiopaque marker at...

...relative location of the proximal and distal end portions of the elongate body.

7 The **system** of claim 5, wherein said at least one indicator comprises a first visible indicator located...

...visible indicator coupled to the proximal end portion of the pull-wire.

5 8. The **system** of claim 1, wherein the delivery assembly comprises first and second delivery members each having...

...the proximal and distal ends is adjusted into the substantially circumferentially looped shape.

9 The **system** of claim 8, wherein the first delivery member is adapted to be positioned within the...

...is adapted to secure the first delivery member within the pulmonary

vein. 1 0. The **system** of claim 9, wherein the anchor comprises ... radially engage the pulmonary vein in order to secure the first delivery member.

1 The **system** of claim 1, wherein the delivery assembly comprises a delivery member with a proximal end...

...at least in part by each spline being adjusted to the second configuration.

12 The **system** of claim 1 1, wherein each spline comprises a single elongate member that terminates along...

...portion of the spline at the coupling to the circumferential support

member. 1 3. The **system** of claim 1 1, wherein each spline comprises a looped member having an apex along...

...extending proximally from the apex along the proximal end portion of the spline.

14 The **system** of claim 13, wherein the circumferential support member is threaded through the apices of the circumferentially spaced splines.

15 The **system** of claim 1 1, wherein the **system** is adapted to

cooperate with an ablation actuator, and: at least one spline is adapted  
...

...couple at least in part the ablation element to the ablation actuator.  
16. The **system** of claim 15, further comprising:  
a proximal coupler located along the proximal end portion...

...the proximal coupler and the ablation element along  
the at least one spline.

17 The **system** of claim 16, wherein  
the ablation element comprises a fluid ablation element;  
the proximal coupler...

...couples the  
ablation element with a fluid source coupled to the proximal coupler.

18 The **system** of claim 16, wherein  
the ablation element comprises an electrical current ablation element;  
the proximal...

...ablation element with a electrical current source coupled to the  
proximal coupler. 19. The **system** of claim 11, wherein the ablation  
element comprises a plurality of individual ablation elements...

...individual ablation element extends along the circumferential support  
member between two  
adjacent splines.

20 The **system** of claim 11, wherein each of the splines comprises a  
material having a memory to the  
second configuration.

21 The **system** of claim 1, wherein the ablation element comprises a  
fluid ablation element.

22 The **system** of claim 1, wherein the ablation element comprises an  
electrical current ablation element.

23 The **system** of claim 22, wherein the electrical current ablation  
element comprises: at least one electrode along...

...to the circumferential area and the electrode via the electrically  
conductive fluid. 24. The **system** of claim 1, wherein the ablation  
element comprises a microwave ablation element.

25 The **system** of claim 1, wherein the ablation element comprises a  
cryogenic ablation element.

26 The **system** of claim 1, wherein the ablation element comprises a  
thermal ablation element.

27 The **system** of claim 1, wherein the **ablation** element comprises a  
light emitting ablation element.

28 A tissue ablation system for treating atrial...

...a circumferential region of tissue at a  
location where a pulmonary vein extends from an **atrium**, comprising:  
a delivery member having a proximal end portion and a distal end portion  
with...

...tissue when the housing is adjusted to the second condition at the location.

29 The **system** of claim 28, wherein in the second condition the distal wall along the circumferential region ...volume of ablative fluid within the fluid chamber to the circumferential area. 0 30. The **system** of claim 29, wherein the porous membrane is adapted to allow the volume of ablative fluid to flow from within the fluid chamber and into the circumferential area.

31 The **system** of claim 29, wherein the ablation element comprises a volume of ablative fluid medium within...

...chamber and that ablatively couples with the circumferential area across the porous membrane.

32 The **system** of claim 29, wherein the porous membrane comprises a porous tetrafluoropolymer. 5 33. The **system** of claim 29, wherein the ablation element comprises an ablative energy source located within the fluid chamber.

34 The **system** of claim 28, wherein the housing comprises an outer jacket with a distal end portion...

...thereby provide distal and proximal orientations, respectively, to the distal and proximal walls.

35 The **system** of claim 34, wherein the outer jacket comprises an elastomeric material.

36 The **system** of claim 28, wherein the housing further comprises a proximal wall which in the second...

...proximally facing surface, and the proximal wall is connected to the distal wall.

37 The **system** of claim 36, wherein the distal and proximal walls are formed from an integral member.

. The **system** of claim 36, wherein the distal wall in the second position further comprises an outer...

...are connected along at least one of the outer and inner circumferential regions.

39 The **system** of claim 36, wherein the distal wall in the second position further comprises an inner...

...inner circumferential region and the circumferential region that includes the distal facing surface.

40 The **system** of claim 28, wherein the mechanical positioning assembly is coupled to the delivery member.

41 The **system** of claim 28, wherein the mechanical positioning assembly comprises an array of splines that are...

...characterize at least in part the first and second conditions for the housing.

42 The **system** of claim 41, wherein the ablation element comprises an energy source that is located along...

...a circumferential region of tissue  
at a location where a pulmonary vein extends from an **atrium**,  
comprising:  
a delivery member with a proximal end portion and a distal end portion  
having...

...is substantially radially collapsed and extends substantially along the longitudinal axis such that the circumferential **ablation** member is adapted to be delivered through a delivery sheath into the **atrium**, and in the second condition the support region of each spline extends at least in **system** of claim 43, wherein each of the splines has a memory to the second condition.

45 The **system** of claim 44, wherein each of the splines comprises a shape-memory material.

46 The **system** of claim 45, wherein each of the splines comprises a nickel-titanium alloy.

47 The **system** of claim 43, further comprising an outer member with a proximal end portion and a...

...adapted to be  
0 withdrawn into the outer member in the first position.

48 The **system** of claim 43, wherein the distal end portion of each of the splines in the second position has  
a radius of curvature away from the longitudinal axis.

49 The **system** of claim 43, wherein the distal end portion of each of the splines in the second position has a radius of curvature toward the longitudinal axis. 5 50. The **system** of claim 43, wherein the ablation element comprises an electrical current ablation element.

51 The **system** of claim 43, wherein the ablation element comprises a thermal ablation element.

52 The **system** of claim 43, wherein the ablation element comprises an ultrasound ablation element.

53 The **system** of claim 43, wherein the ablation element comprises a microwave ablation element

54 The **system** of claim 43, wherein the ablation element comprises a thermal ablation element.

55 The **system** of claim 43, wherein the ablation element comprises a cryoablation element.

56 The **system** of claim 43, wherein the ablation element comprises a fluid ablation element.

57 The **system** of claim 43, wherein the **ablation** element comprises a light emitting ablation element.

58 A tissue ablation system for treating atrial...

...a circumferential region of tissue at a

location where a pulmonary vein extends from an **atrium**, comprising:  
a delivery member with a proximal end portion and a distal end portion  
having...

...condition the contact member is adapted to be delivered through a  
delivery sheath into the **atrium**, and wherein in the second condition  
the contact member comprises a circumferential wall that  
surrounds the longitudinal axis; and  
an **ablation** element having an ablative energy source that is located  
along the distal end portion, wherein...

...when the contact member is adjusted to the second condition at the  
location.

59 The **system** of claim 58, wherein the contact member comprises an  
inflatable balloon, the circumferential wall comprises...

...the outer skin of the balloon and into the circumferential region of  
tissue.

60 The **system** of claim 58, wherein the ablation element comprises a  
thermal ablation element.

61 The **system** of claim 58, wherein the ablation element comprises an  
ultrasound ablation element.

62 The **system** of claim 61, wherein the ultrasound ablation element  
comprises an ultrasound transducer assembly mounted onto...

...to the longitudinal axis and through the circumferential wall of the  
contact member.

63 The **system** of claim 62, wherein the ultrasound transducer assembly  
comprises a conically shaped  
transducer with an outer conical surface having a distal orientation.

64 The **system** of claim 62, wherein the ultrasound transducer assembly  
comprises a curved distal face. 1 5 65. The **system** of claim 62, wherein  
the ultrasound transducer assembly comprises at least one ultrasound  
transducer panel...

...is adapted to emit the circumferential pattern of energy with the distal  
orientation.

66 The **system** of claim 65, wherein the transducer panel is adjustable  
with an expandable member located between the panel and the distal end  
portion of the delivery member.

67 The **system** of claim 66, wherein the expandable member comprises a  
balloon.

68 The **system** of claim 66, wherein the expandable member comprises a  
cage.

69 The **system** of claim 58, wherein the ablation element comprises a  
microwave ablation element

70 The **system** of claim 58, wherein the ablation element comprises a  
cryoablation element.

71 The **system** of claim 58, wherein the ablation element comprises a

fluid ablation element.

72 The **system** of claim 58, wherein the **ablation** element comprises a light emitting ablation element. -7 1

Diagnose Patient with

**Atrial Arrhythmia**

2-

Form a Circumferential Conduction Block  
along a Circumferential Region of Tissue  
in a Pulmonary...

...2B

/-D

FIG\* 2C FIG 2D

d d

D

dw

FIG 9 2E

Position Guiding **Catheter** Tip

into Left Atrium From Right

Atrium and Through Fossa Ovalis

Advance Distal End Portion of

**Guidewire** out Guiding **Catheter** Tip

and into Pulmonary Vein ("PV")

Advance Distal End Portion of

Circumferential Ablation **Catheter**

over **Guidewire** and into

Pulmonary Vein

Position Ablation Element Adjacent

to an Ablation Region along PV wall...

...Formed

----- .....

Ablate a Circumferential Region of Tissue

in the PV wall which Circumscribes the

PV **Lumen** and which Transects the PV

FIGe3

:@@ 5@

100 -

MO 142

175 130 101 132 '

(D...j

195

1901 FIG 9 BD

of

I

C) . CD

FIG. aF

Form a First **Linear Lesion** in Tissue Extending

Along a Left Atrial Wall and Between and

Including a First Pulmonary Vein ("PV") ostium

and a Second Pulmonary Vein ostium

Form a Second **Linear Lesion** in Tissue Extending

Along the Left Atrial Wall and Between and

Including the First PV ostium and

a Third PV ostium

Form G Circumferential **Lesion** Along a

Circumferential Path of Tissue in the

PV wall of the First Pulmonary Vein

which circumscribes the PV Lumen  
 which intersects both the First  
 and the Second Linear Lesions  
 FIG\* 9A  
 58 50@5@4  
 59  
 I  
 FIG \* 9B  
 0@5@4  
 57 450...  
 ...mv.  
 FIG\* 9H  
 .....  
 Monitor Electrical Conduction Signal  
 Along Pulmonary Vien (TV) Wall  
 with Signal Monitoring System  
 8  
 Engage  
 NO ..rr y mogen  
 Different  
 Si nal?  
 Pv  
 y  
 Identify Location of Arrh thmogenic  
 Origin Along Longitudinal Axis  
 of the PV  
 .....t .....  
 Position Ablation Element Adjacent to an  
 Ablation Region that either includes  
 the Arrhythmogenic Origin or is Between  
 the Origin and the Left Atrium  
 .... Ablate a Circumferential Region of Tissue  
 i Fire Test Stimulus  
 I Along the PV wall at the Ablation Region  
 lAbove Ablation Region,'  
 A long PV wall  
 Monitor Electrical Conduction S'ignals  
 L----- Along PV wall Between Ablation Region  
 and the Left Atrium  
 @10  
 NO Conf irm  
 onductio  
 Block?  
 FIG a 10  
 w  
 LT 1  
 550 572 572...  
 ....IPC) or to both national classification and IPC  
 B. FIELDS SEARCHED  
 Minimum documentation searched (classification system followed by  
 classification symbols)  
 IPC 7 A61B A61M  
 Documentation searched other than minimum documentation to...368 A (MED  
 INSTITUTE, INC.) 1128,439  
 26 February 1992 (1992 26) 58  
 column 1, line 47 -column 2, line 15;  
 figure 1  
 A US 5 687 723 A (AVITALL) 19289439  
 18 November 1997 (1997 18) 58



column 9, line 66 -column 10, line 22;  
figures 16,17

El Further documents are listed in the continuation of box C...

22/3,K/49 (Item 49 from file: 349)  
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*Some of the inventors*

00571990 \*\*Image available\*\*

RADIO-FREQUENCY BASED CATHETER SYSTEM AND HOLLOW CO - AXIAL CABLE  
FOR ABLATION OF BODY TISSUES  
CATHETER DIFFUSEUR D'ONDES RF ET CABLE COAXIAL CREUX SERVANT A L'ABLATION  
DE TISSUS CORPORELS

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DE TISSUS CORPORELS

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Detailed Description  
Claims

English Abstract

An improved radio frequency catheter system for ablating biological tissues of body vessel in a patient including a catheter (3), a deployable antenna guide (36) disposed at the distal portion of the catheter, and a radio-frequency ("RF") antenna (54) mounted on the antenna guide. The RF antenna includes an axial passageway to accommodate the antenna guide, is adapted to receive, and transmit RF energy for tissue ablation. Upon deployment, the antenna guide acquires a loop configuration which establishes line contact with the body vessel conformable to its internal contour to prescribe the precise, and affixed tissue ablation pathway despite body vessel movements. The RF antenna is carried by the antenna guide to be deployed along the established tissue ablation pathway. Alignment of the loop with the desired tissue ablation pathway is facilitated with the use of radiopaque markers, and intra-cardiac electrodes mounted along the antenna guide. The catheter, as well as the antenna, can be provided with steering or deflection mechanism for navigation through the body vessel passageways. A hollow coaxial cable is provided for the delivery of RF energy.

#### French Abstract

L'invention porte sur un **catheter** diffuseur d'ondes RF servant a l'ablation de tissus biologiques comportant un **catheter** (3) proprement dit s'introduisant dans un vaisseau du patient, un guide d'antenne deployable place a l'extremite distale du **catheter**, et une antenne RF (54) montee sur le guide d'antenne. L'antenne RF, qui...

...marqueurs opaques, et par des electrodes intracardiaques disposees le long du guide d'antenne. Le **catheter**, de meme que l'antenne, peuvent etre munis de mecanismes de guidage ou d'inflexissement...

#### Detailed Description

Radio-Frequency Based. **Catheter System**  
and Hollow **Co - Axial Cable**  
for Ablation of Body Tissues  
The present application is a continuation-in-part of U...

...frequency ("RF")  
powered medical apparatus and ablation of biological tissues.

More particularly, this invention concerns **catheter**-based **RF antenna** for **ablating** biological tissues within the body vessel of a patient and for the treatment of **cardiac arrhythmias**.

In recent years medical devices have gained significant acceptance in the medical community as an...

...the treatment of cardiac diseases. The first has been the shift from open-heart surgical **procedures** to less invasive and less expensive **catheter**-based treatments, which are safer and less debilitating. The second trend is represented by the shift from the use of anti-**arrhythmic** drugs to minimally invasive **catheters** or other device-based therapies to palliate incurable **arrhythmias**.

For example, automatic cardioverter-defibrillator are routinely implanted in patients with lethal **ventricular arrhythmias** to reduce the likelihood of sudden death. Thus, **radio - frequency** (**RF**) **catheter ablation** is now being performed in large number of patients suffering from **cardiac arrhythmias**.

Despite these advances in technology,, **atrial fibrillation** ("AF") remains a significant challenge. AF, a rapid irregular rhythm in the atria or upper...

...and heart attack and a major health care burden. To date, the most effective surgical **procedure** for the treatment of AF has been the Maze **procedure** undertaken in "open-heart" surgery. In the Maze **procedure**, incisions are made along **lines** determined exterior of the atrium, which are then sutured together. As healing develops, **scars** are formed along the incision **lines** thereby forming barriers to the conduction of electrical impulses. By creating such barriers, AF can no longer be sustained and regular heart rhythm is restored.

However, the Maze **procedure** has not been widely adopted due to the morbidity and mortality associated with open-heart...

...of  
the chest bones.

One new approach to mimic the Maze operation is represented by **catheter** -based radio-frequency ablation **technique** , wherein, instead of surgical incisions, a **catheter** -electrode is applied to destroy or **ablate** the heart tissues inside the **atrial** chamber. The **catheter** -electrode is passed through the artery

J

for access to the atrium, as commonly practiced in the medical.

field. Within the atrium, the tip of the **catheter** -electrode is positioned, usually with the aid of x-ray or fluoroscopic means, and is...

...is required. At this spot, the tissue is destroyed by resistive heating generated from the **catheter** -electrode. Thereafter, the **catheter** -electrode is repositioned to the next spot for ablation. A series of spot ablations thus mimics the lineal **lesions** as accomplished under the Maze **procedure** against the conduction of electrical impulses.

Existing **catheter** -based **ablation** **procedures** are recognizably less intrusive than "open-heart" surgery. In addition, during the **ablation** , disruption of **cardiovascular** function is reduced. However, a successful **catheter** -based **radio - frequency ablation procedure** requires the **ablation** of tissue spots within the spatial or proximity tolerance between adjacent spots, usually less than...

...passage of electrical impulses. In that connection, the task for the precise placement of the **catheter** -electrode represents a critical element of a successful **procedure** .

A major drawback of such existing **procedures** is in the time-consuming task in positioning the **catheter** -electrode at the desired **ablation** spots within the **atrium** while the heart chamber muscles are pulsating. Movement-s of **atria** ! wall or the heart muscles often render accurate placement of the **catheter** electrode difficult, and slippage of the **catheter** -electrode tends to occur thereby damaging portions of the **atrium** where **ablation** is not desired. As a result, placement of the **catheter** based RF **ablation** cannot be efficiently accomplished, and prolonged **procedure** time, in excess of 12 hours, can be expected. Further, during the **procedure** , x-ray or other irradiating means are routinely employed for locating and positioning the **catheter** -electrode, which dictates the use of heavy lead protective gear by the electro-physic-logist. As a result, such inconvenience is often amplified by the prolonged **procedure** time, which detracts from the use of **catheter** -based electrode as an efficient means for tissue ablation.

To minimize the risk of slippage, for example, in U.S.

Patent No. 5,741,249, a **catheter** -based **microwave antenna** is disclosed wherein a distal tip is incorporated into the **antenna** to anchor it to the **atrial** wall. However, while this design reduces the likelihood of **antenna** or **catheter** -electrode slippage during each **ablation** step, it does not eliminate the consuming task to secure precise placement of the **antenna** along the

desired ablation path for each ablation step. Thus after each ablation step, the **antenna** has to be re-positioned and anchored precisely at the next spot which must be located within the spatial or proximity tolerance on the **ablation** path as referenced above.

Accordingly, effective treatments for **atria** ' **fibrillation** with **catheter ablation** will require the creation of long or overlapping lineal or curvilinear **ablation** lesions on the inner surface of the **atrium** . These **lesions** can then act as barriers to the conduction of electrical impulses, thus preventing **atrial fibrillation** .

It is also recognized that a critical requirement for the effective **catheter** -based **ablation** of **atrial fibrillation** is the ability to stabilize and anchor the **catheter** and **microwave antenna** inside the **atrial** chambers. New **catheter ablation** systems, preferably capable of producing long or overlapping lineal or curvilinear **ablation** lesions , are required for the development of minimally invasive **catheter** -based curative **procedures** for **atrial fibrillation** .

The present invention provides a design of such a **catheter system** , which can be used not only for **atrial fibrillation** but for **ablation** of biological tissues in other body vessels. The **catheter system** contains stabilizing and anchoring mechanisms employing monorail and **looped antenna** guide, sensors for monitoring different parameters during ablation, and handle with control slides for easy steering and manipulation of the **catheters** .

#### SUMMARY OF THE INVENTION

According to the present invention, an improved **radio frequency catheter system** is provided for **ablating** biological tissues of a body vessel, including the **atrium** of a patient.

The **catheter system** comprises a **catheter** that is adaptable for insertion into the body vessel and a deployable **antenna** guide disposed within the **catheter lumen** . A deployable radio-frequency **antenna** , together with a hollow **co - axial cable** , is provided at the distal portion of the **catheter** to receive and transmit radio-frequency energy for tissue ablation. In a representative embodiment of the invention, the **antenna** includes a helical coil and has an axial passageway to accommodate the **antenna** guide, which, upon deployment prescribes the ablation pathway of the **antenna** for tissue ablation. The **antenna** guide includes elongated portions which are secured to control slides for positioning and deployment control. The **antenna** guide is deployable within a body vessel to form a **loop** configuration that is conformable to the contour of the body vessel.

Alignment of the loop...

...is facilitated with the use of radio-opaque markers and intracardiac electrodes mounted along the **antenna** guide. After the **loop** is formed within the body vessel, the radio-frequency **antenna** will be deployed along the **antenna** guide for tissue ablation.

In an alternate embodiment of the present invention, one of

the elongated portions of the **antenna** guide is secured to a positioning control slide, and the other portion is secured to the distal portion of the **catheter**. As a further alternate embodiment of the invention, the **antenna** guide is formed as an elongated flexible member having a detached distal end portion that is terminated with a distal tip.

The radio-frequency **catheter system** of the present invention can also incorporate various alternate radio-frequency **antenna** designs. In one such alternate embodiment of the present invention, the radio-frequency **antenna** comprises a monopole bead disposed at the distal portion of the **catheter** for delivering an optimal radiation pattern while minimizing reflection and voltage standing wave ratios.

in another alternate embodiment of the present invention, a microstrip flexcircuit is provided..

In application, the **antenna** guide is deployed out of the **catheter lumen** to establish contact with the interior surface of the body vessel. The flexibility of the **antenna** guide enables it to flex to conform to the contour of the body vessel to define the ablation pathway for the radio-frequency **antenna**.

The present invention effectively reduces if not avoids the need for repetitive pin-point precision placement of the ablation **catheter** electrode of the prior art. The present invention conveniently places the radio-frequency **antenna** along the locus of an **antenna** guide which defines the tissue ablation pathway. At the same time,, the present invention ensures...

...of the prior art. Accordingly, the present invention substantially accomplishes the objective of the Maze **procedure** in achieving **curvilinear lesions** yet without the need for open-heart surgery.

These and other aspects and advantages of...

#### ...BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a conceptual diagram of a radio-frequency **catheter** ablation **system** of the present invention, together with radio-frequency power module, computer control and data recording device.

Figure 2 is a perspective view of the radio-frequency **catheter** ablation **system** of the present invention.

Figure 3A is a sectional view of the **antenna** guide and the radio-frequency **antenna** in a deployed position at the distal

portion of the radio-frequency **catheter** ablation **system**. Figure 3B is a sectional view of the **antenna** guide and the radio-frequency **antenna** in a retracted position at the distal portion of the radio-frequency **catheter** ablation **system**.

Figure 4A is a partial sectional view of the distal portion of the radio-frequency **catheter** ablation **system**.

Figure 4B is a partial sectional view of the distal portion of another embodiment of the radio-frequency **catheter** ablation **system**.

Figure 5 is sectional view of the radio-frecfuency **antenna** and a partial view of the **antenna** guide.

Figure 6 is a cross-sectional view taken from. line 6-6 of Fig. 5.

Figure 7 is a perspective view of another embodimen: of...

...present invention.

Figure 8 is a typical cross-sectional view of distal portion of the **catheter system**.

Figure 9 is a plan view of a microstrip used for electrical connection between the radio-frequency **antenna** and a source of the radio-frequency energy.

Figure 10 is an elevational view of the microStrip of Figure 9.

Figure 11 is a partial sectional view of the radiofrequency **catheter ablation system**.

Figure 12 is a partial sectional view of a handle chassis used in the radio-frequency **catheter ablation system**.

Figure 13 is a cross-sectional view of the microstrip disposed within the handle chassis...

...sectional view of another embodiment of present invention incorporating a design of a monopole radiofrequency **antenna**.

Figure 15 is a partial sectional view of another embodiment of the present invention incorporating a design of a microstrip flexcircuit radio-frequency **antenna**.

Figure 16 is a cross-sectional view of the miCrostrip flexcircuit taken from line 16-16 of Fig. 15.

Figure 17 is a partial cut-away view of the dista" portion of a hollow cable of tline oresent invention for use in a radiofrequency **catheter ablazion system**.

Figure 18 is a partial sectional view of the d'ls-L-.al portion of the **catheter** of the present invention incorporating one or more steering wires.

Figure 19 is anothler partial sectional view of the distal portion of the **catheter** of the present inventicr deflected by one or more steering wires.

#### DETAILED DESCRIPTION OF THE INVENTION

The current invention provides an improved radio frequency based **catheter system** for ablating biological tissues within the body vessel of a patient. The **system** includes a **catheter** that is adaptable for insertion into a body vessel of patient. it incorporates a deployable radio- frequency **antenna** for delivering electromagnetic energy to the treatment site. A monorail guide is provided for precise positioning of the

**antenna** along a desired ablation pathway. The present invention also provides a hollow **co - axial cable** for conducting electromagnetic energy.

As seen in Figs. 11, 2, and 3, the present invention comprises a **catheter** 3, which is adapted for insertion into a body vessel of the patient. The **catheter** has a flexible elongated tubular body 10 with a proximal portion 12 and a distal portion 14. A **lumen** 16 extends from the proximal portion of the **catheter** to the distal portion with a distal opening 18 (Figs. 3 and 4). Located at the proximal portion 12 of **catheter** 3 is a handle chassis 20 for housing necessary steering and positioning controls, as will be described in further details below. Incorporated at the proximal end of the **catheter** 3 is a coupling 22 for connecting various electrodes (not shown) in support of the ablation **procedure**.

The dimensions of **catheter** 3 are adapted as required to suit the particular medical **procedure**, which are well known in the medical art. The tubular body 10 of the **catheter** is generally constructed of polymer materials that are bio compatible within the body vessel environment...

...r dn e s S and elasticity.

In one embodiment of the present invention, the **catheter** 3 is formed with a plurality of segments using one or more of the afore-mentioned materials such that the **catheter** bodill is progressively more flexible toward its distal end. The segments are joined together via...

...tubular body 10 to attain the desirable level of stiffness and torsional strength for the **catheter**. This allows the **catheter** -IL--3 advance and negotiate through the body vessel of a patient, and to enable...

...the proximal L -o IL---he distal portion. portion t

The distal portion 14 of **catheter** 3 consists of a softer polymer compound with little or no h@rading to provide the desired flexibility to accommodate distal deflection or steering of the **catheter** 3 when it is maneuvered through the narrow passageways of body vessels such as arteries or veins. In the present invention, steering of the **catheter** is implemented by a pull wire 30, which extends from the control handle chassis 20 to the distal portion 14 of the **catheter** 3, as shown in Fig. 11.

2 5 At the dkistall end of **catheter** 3, pull wire 30 is affixed to the inner wall of the **catheter** **lumen** 16 by soldering or other suitable means.

Pull wire 30 is proximally fastened to deflection...

...of the thumb slide 32 along slot 34, together with the torsional movement of the **catheter** 3 enables a physician to bend or straighten the **catheter** 3 as needed in order to negotiate through the passageways of the body vessel. Incorporated...



...available. Examples of such means include set-release, pressure switch or self-locking mechanisms.

The **catheter system** 1 of the present invention provides an effective means for guiding a R-7 **antenna** for tissue ablation along a predetermined ablation pathway. Figs. 'IL I 3A, 42@. and 4B show an **antenna** guide or monorail 36, which is deployed in an extended position adjacent the distal portion 14 of **catheter** 3.

The **antenna** guide or monorail 36 is also adaptable to be retracted within the **catheter lumen** 16 as shown in Fig. 35B.

In one embodiment of the present invention, monorail 36...

...of a strip-like material. Alternatively, monorail 36 can also be made of small-diameter **tubing**, as shown in the drawings.

Monorail 36 has extended portions 42 and 44 which extend proximally within the **catheter lumen** 16 (Figs. 4A, 8 - 10). At the handle chassis 20, monorail extension portions are secured to respective control slides 46 and 48. Similar to the **catheter** deflection pull wire 30, control slides 46 and 48 are slidably engaged within longitudinal slots...

...in Fig. 2, and are moveable distally or proximally along the longitudinal axis of the **catheter** 3. Thus by moving one or both control slides, the monorail guide can establish a U-shaped fashion within the **catheter lumen** 16 at the distal portion 14 of the **catheter** 3. A smooth or curved tip 40 is provided at the monorail 36 such that in the retracted position, tip 40 substantially closes the distal opening 18 of **catheter** 3 to isolate the **catheter lumen** 16 from the biological environment.

The tip 40 also renders the **catheter** "atraumatic" and provides a smooth distal profile for the **catheter** to reduce the risks of body vessel puncture as it is navigated through the passageways...

...and flexibility. These structural properties allow monorail 36 to be moved without crinkles within the **catheter lumen** 16. However, in its deployed positio.- OUTS4 a -I-de the **catheter lumen** 16, the monorail 36 is adaptable to flex.

Monorail 36 is deployable beyond the distal opening 18 of the **catheter** 3 within a body vessel to form a substantially continuous loop 50 as shown in...

...with the longitudinal advancement of control slides 46 and 48 toward the distal end of **catheter** 3 such that the monorail extends beyond the **catheter** distal opening 18 to establish contact with the interior wall- of the body vessel. Upon...

...portion of the loop 50 bears against the wall of the body vessel thereby acquiring **line** contact with the interior wall of the body vessel in spite of its possible movements...

...ray or f'luoroscopic fiCat4 examination, thereby aiding the identi -Lon of its position during **catheter** insertion or tissue ablation. The

structure and use of radio-opaque markers are well-known in the art, and are not detailed here.

As a variation in design, the **antenna** guide can be constructed of two separate elongated members joined at the distal tip to...  
...particular application.

Thus by way of example, a low profile (having ultra small cross-section) **catheter** used in operation within a narrow lumen of a body vessel could require a relatively small joint angle for the elongated members...

...the present invention, wherein one end of the monorail guide 36a is secured to the **catheter** 3 adjacent the distal opening 18.

The other end of the monorail 36a, which incorporates...

...control slide at the handle chassis.

The present invention includes a radio-frequency (RF) **antenna** 54 disposed adjacent the distal portion 14 of the **catheter** 3, as shown in Figs. 2 - 7, for tissue ablation. In an representative embodiment of the present invention, the RF **antenna** 54 includes an electrically conductive material or wire strip that is wound in a helical...

...wire strip are a matter of design choice, which can vary according to the particular **procedure** requirements as known in the art. Thus these design elements and considerations are not detailed here.

As shown in Figs. 2, 3 and 4A and 4B, the RF **antenna** 54 includes the helical coil 56, which defines an axial passageway 58 for accommodating the monorail 36. The RF **antenna** 54 is slidably mounted over the monorail 36. Thus its movement will be prescribed by the monorail.

To enhance its shape integrity, RF **antenna** 54 is provided with a tubular liner or sleeve 60, which has a flexible extended body extending from the helical coil 56 proximally toward the proximal portion 12 of the **catheter** 3. Sleeve 60 is constructed of a dielectric material, which reduces the likelihood of which is slidably secured to the handle chassis for the axial displacement of the RF **antenna** at the proximal portion, as will be discussed in more details below. The extended portion...

...monorail 36 extends proximally within the passageway 58 to the proximal portion 12 of the **catheter** 3. Thus the present invention provides for a set of electrical conductors each of which...

...56 proximally to the handle chassis 20 for the delivery of RF energy.

The RF **antenna** 54 is adapted to receive and radiate electromagnetic energy from a source of radio-frequency...

...is that of the microwave frequency ranging from approximately

300 mHz and up. The RF **antenna** is capable of applying substantially uniformly distributed electromagnetic field energy transmitted by the helical coil...

...of the electromagnetic field transmitted is substantially normal to the longitudinal axis of the RF **antenna**, and therefore producing uniform energy field circularly about and bounded by the **antenna**. The energy delivered for the ablation will be uniformly distributed along the **antenna**, which is independent of the contact between the **antenna** and the tissue to be ablated. As a result, the present invention reduces the likelihood...

...proximity or in contact during ablation in comparison to the spot conductive or resistive ablation **catheter** of the prior art.

At the handle chassis 2.0, the inner conductor 64 and...

...13). Junction plates in turn are coupled to an electrical conductor 82, for example solid **co-axial cable**, which extends from the handle chassis 20 to a source of electromagnetic energy (not...

...wire connector 22. At the microstrip, monorail 36 exits the sleeve 60 of the RF **antenna**, which enables --E to be connected to one of control slides.

Microstrip 80 is slidably...

...housed with the handle chassis 20. To provide for the axial movement of the RF **antenna**, cable 82 can be moved distally or proximally relative to the handle chassis for the...

...terminate into the signal pins (not shown) provided for in the wire connector 22.

The **catheter** is adaptable to be inserted through an opening into a body vessel of a patient...

...tissue for ablation. Prior to the insertion,, both the guide member 36 and the RF **antenna** 54 are retracted within the **catheter lumen** 16 with the radio-opaque marker 40 to attain an atraumatic tip configuration for the **catheter** to facilitate smooth passage. The distal portion 14 of the **catheter** 3 is then inserted into the body opening and is manipulated to reach within the...

...the handle chassis and the use of the deflection contro'! K.

Placement of the RF **antenna** guide member or monorail 36 is facilitated by the radio-opaque marker 40, whose position...

...or fluoroscopic means, as practiced in the art. After the distal portion 14 of the **catheter** 3 is placed within the proximity of the tissue ablation site, the monorail is moved distally by the control slides so it exits the **catheter lumen** opening 16 to acquire an extended or a deployed position loop configuration as described above...

...use of the intracardiac ECG electrodes 96 for the physician to align the RF antenna guide or monorail 36 with the desired ablation pathway.

By way of example, in the case of an atrium of the heart, the size of loop 50 can be adjusted to conform to the...

...least a portion of the loop 50 to rest upon the atrial wall, which establishes line contact between the atrium and the monorail. The flexibility of the monorail 36 allows at...

...control slides 46 and 48 are secured in position at the handle control. The RF antenna 54 is then moved distally to exit the distal end opening of the catheter and slidably guided by the monorail to reach the precise location where ablation is needed...

...ablation can be accomplished with the application of radio-frequency energy. Depending on the particular procedure requirements, the length of the ablation can be adjusted by positioning the RF antenna along various locations along the loop followed by applications of the RF energy. Thus, long and contiguous ablation lines can be established to substantially eliminate the risk of electrical impulse leakage between ablated tissue pathways.

The above steps can be repeated for other locations within the atrium as necessary depending on the particular procedure requirements.

Fig. 7 shows another embodiment of the present invention which incorporates a variation of the antenna guide design. In this embodiment, the antenna guide 102 comprises an elongated flexible member having a detached distal end portion 104 that...

...106 is incorporated with a radio-opaque material to aid in the placement of the catheter as described above. The other end portion of the guide 102 extends proximally to a...

...control slide (not shown) in a similar fashion as the embodiments described, above.

Similarly, the antenna guide 102 can be retracted within the lumen of the catheter 100 prior to its deployment,,, together with a RF antenna 110.

In application, after the catheter 100 is placed within the proximity of the tissue to be ablated, the antenna guide 102 is deployed out of the catheter lumen 108 where the distal tip 106 is allowed to anchor within crevices on the surface of the body vessel. The flexibility of the antenna guide 102 enables it to flex to conform to the contour of the body vessel and to establish line contact between the guide 102 and the body vessel. As a result,, any relative movement between the guide 102 and the body vessel can be minimized. Thereafter, the RF antenna 110 is carried by the antenna guide 102 to be extended out of the catheter lumen 108 for the ablation along a pathway that is substantially aligned in parallel with the line contact

between the antenna guide 102 and the body vessel.

As alternative embodiments, the radio-frequency antenna of the present invention can incorporate various designs of radio frequency antennas. Fig. 14 illustrates one such alternative embodiment. As shown in Figs. 14, in lieu of the helical coil configuration as described above and in lieu thereof, the catheter system is provided with an antenna 120 which comprises a monopole bead 122. The monopole bead is disposed circumferentially over sleeve 60 at the distal end portion of antenna 120. Sleeve 60 has a lumen 58 to accommodate a guide member, such as the guide member or monorail 36 or antenna guide 102, as described above.

The monopole bead is connected to inner conductor 64, which...

- ...is generated between the monopole bead 122 and the outer conductor 66 external to the antenna, which can be applied for tissue ablation. Thus, though there is no physical contact between...
- ...art to effect an impedance matching function that provides smooth impedance transition between the transmission line that supplies the RF energy and the medium to which the ...dimensions of the monopole bead 122 are designed to minimize RF reflection coefficient of the antenna system and therefore minimizing VSWR to approximately 1:1. By way of illustration, the diameter of...
- ...of the electromagnetic field transmitted is substantially normal to the longitudinal axis of the RF antenna, and therefore producing uniform energy field circularly about and bounded by the antenna. As a further alternative embodiment of the present invention, the radio-frequency antenna can incorporate the design of a microstrip flexcircuit in lieu of the helical coil or...
- ...as described above. As shown in Figs. 15 and 6, a microstrip flexcircuit antenna 134 includes a pair of spaced apart electrically conductive microstrips 134 and 136 disposed at the distal portion of the antenna on a dielectric backing 69 as part of the dielectric coating material 68 used...
- ...be achieved in the art. Accordingly, it is preferable that the microstrip flexcircuit antenna be designed to minimize the reflection VSWR, as known in the art. The dimensions of...
- ...in connection to one or more electrodes 142 at the distal portion of the RF antenna 138 of the present invention to provide a means for obtaining optimal tissue proximity and electrical conductivity measurements before and after tissue ablation.

Additionally, the antenna of the present invention can include one or more antenna deflection or steering wires affixed at distal portion of the antenna to achieve more pronounced shape or curvature of the antenna. Figs. 18 and 19 illustrate an exemplary embodiment where a deflection wire 144 is affixed to the distal end portion 146 of the antenna 138 and extends

proximally within the internal **lumen** of the hollow **coaxial Cable** to be attached +Co and controlled by - a deflection control mechanism at the handle (not shown) The attachment of the deflection wire 144 at the end portion 146 of the **antenna** permits amplified deflection of the **antenna** at that location, as illustrated in Fig In application, the **antenna** 138, provided with such deflection means, can be deployed into the body **lumen** with the aid of the guide member or monorail 36 as described above. Where necessary...

...actuation of the deflection wire 144 to effect an amplified deflection in the radio-frequency **antenna**. As a result, the **antenna** can be shaped in such a way so as to be adaptable to gain access...

...reduces if not eliminates the need for repetitive pin-point precision placement of the ablation **catheter** electrodes of the prior art. The present invention conveniently places the RF **antenna** along the locus of an **antenna** guide which defines the tissue ablation pathway. At the same time, the present invention ensures...

...of the prior art. Accordingly, the present invention substantially accomplishes the objective of the Maze **procedure** in achieving lineal **lesions** yet without the need for open-heart surgery. While the above description of the invention...

#### Claim

... radio-frequency energy comprising a first inner elongated electrically conductive tubular member having an axial **lumen** and a second elongated electrically conductive tubular member disposed in a substantially coaxial relationship over...

...conductive members is formed of an electrically conductive thinfilm material.

6 A radio-frequency-based **catheter system** for ablating biological tissues within the body vessel of a patient comprising:

- a) a **catheter** adapted for insertion into the body vessel of the patient,, the **catheter** having a proximal portion, a distal portion with an distal opening and a **lumen** extending from the proximal portion to the distal portion;
- b) an elongated **antenna** guide disposed within the **catheter lumen** and deployable beyond the distal opening of the **catheter** to form a loop substantially conformable to the internal contour of the bo-a-v vessel; and
- C) a radio-frequency **antenna** disposed at the distal portion of the **catheter** and having a passageway to accommodate the **antenna** guide passing slidably therethrough, the radio-frequency **antenna** being adaptable to receive and radiate radio-frequency energy for ablating the biological tissues along a biological ablation pathway.

7 The **catheter system** according to claim 6, which further comprises electrical conductors electrically coupled to the radio-frequency **antenna** and extending proximally toward the proximal portion of the **catheter** within its **lumen**.

8 The catheter system according to claim 7 wherein the electrical conductors are adapted to conduct radiofrequency energy.

9 The catheter system according to claim 6, wherein the radio-frequency antenna further comprises a tubular sleeve defining the axial passageway.

10 The catheter system according to claim 7, wherein at least one of the electrical conductors is formed of an elongated tubular material.

11 The catheter system according to claim 7 wherein the electrical conductors are each formed of an elongated tubular...

...a substantially coaxially aligned relationship with each other to form a hollow cable.

12 The catheter system according to claim 7, wherein at least one of the electrical conductors is formed of an electrically conductive wire-mesh material.

13 The catheter system according to claim 7, wherein at least one of the electrical conductors is formed of an electrically conductive braided material.

The catheter system according to claim 7, wherein at least one of the electrical conductors is formed of an electrically conductive thin-film material.

15 The catheter system according to claim 6, wherein the antenna guide has extended portions extending proximally within the catheter lumen.

16 The catheter system according to claim 6, wherein the antenna guide is constructed of tubing material.

17 The catheter system according to claim C", which further comprises at least one intracardiac electrocardiogram electrodes mounted within the antenna guide.  
is.

18 The catheter system according to claim 6, wherein the antenna guide is constructed of a plurality of elongated members joined to form a unitary monorail.

19 The catheter system according to claim 6 wherein the antenna guide further comprises at least one distal tip formed of radio-opaque material.

20 A radio-frequency-based catheter system for ablating biological tissues within the body vessel of a patient comprising:

- a) a catheter adapted for insertion into the body vessel of the patient, the catheter having a proximal portion, a distal portion with an distal opening and a lumen extending from the proximal portion to the distal portion;
- b) an elongated antenna guide slidably disposed within the catheter lumen and having a first end portion secured to the distal portion of the catheter and a second end portion extending proximally within the catheter lumen, the antenna

guide being deployable beyond the distal opening c-f the **catheter** to form a loop having a portion conformable to the interior contour of the body vessel; and  
c) a radio-frequency **antenna** disposed at the distal portion of the **catheter**, the **antenna** having an axial passageway to accommodate the **antenna** guide passing therethrough, the radio-frequency **antenna** being adaptable to receive and generate radio-frequency energy for ablating the biological tissues along a biological ablation pathway.

21 A radio-frequency-based **catheter**, **system** for ablating biological tissues within the body vessel of a patient comprising:

a) a **catheter** adapted for insertion into the body vessel of the patient,, the **catheter** having a proximal portion, a distal portion with an distal opening and a **lumen** extending

from IC-he pr

lmal portion to the distal portion;

b) an elongated flexible **antenna** guide slidably disposed within the **catheter** **lumen** and deployable beyond the distal opening of the **catheter** forming line contact with the body vessel and substantially conforming to the contour of the body vessel to define a biological ablation pathway; and

c) a radio-frequency **antenna** disposed at the distal portion of the **catheter**, the **antenna** having an axial passageway to accommodate the **antenna** guide passing therethrough, the radio-frequency **antenna** being adaptable to. receive and transmit radio-frequency energy for ablating the biological tissues along the ablation pathway.

22 The **catheter** **system** according to claim 21 wherein the **antenna** guide further comprises at least one distal tip formed of radio-opaque material.

23 The **catheter** **system** according to claim 21 wherein the **antenna** guide is constructed of tubular material.

24 The **catheter** **system** according to claim 20, wherein the radio frequency **antenna** comprises a helical coil defining the passageway to accommodate the **antenna** guide passing slidably therethrough,

25 The **catheter** **system** according to claim 21, wherein the radio frequency **antenna** comprises a helical. coil defining the passageway to accommodate the an4enna guide passing slidably therethrough.

26 The **catheter** **system** according to claim 20, wherein the **antenna** comprises a microstrip flexcircuit having a passageway to accommodate the **antenna** guide passing slidably therethrough.

27 The **catheter** **system** according to claim 21, wherein the **antenna** comprises a microstrip flexcircuit having a passageway to accommodate the **antenna** guide passing slidably therethrough.

28 The **catheter** **system** according to claim 2b, wherein the



**antenna** comprises a monopole circumscribing the tubular sleeve.

29 The **catheter system** according to claim 21, wherein the **antenna** comprises a monopole circumscribing the tubular sleeve.

2 0

30 The **catheter system** according to claim 6,, which further comprises at least one elongated deflection wire affixed at the end portion of the **antenna** and extending proximally of the **antenna** , the deflection wire being adaptable to attain the deflection of the end portion of the **antenna** .

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SYSTEM AND METHOD FOR MAGNETIC-RESONANCE-GUIDED ELECTROPHYSIOLOGIC AND  
ABLATION PROCEDURES

SYSTEME ET TECHNIQUE PERMETTANT D'EXECUTER DES PROCEDURES D'ABLATION  
ET D'ELECTROPHYSIOLOGIE GUIDEES PAR RESONANCE MAGNETIQUE

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SYSTEM AND METHOD FOR MAGNETIC-RESONANCE-GUIDED ELECTROPHYSIOLOGIC AND  
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ET D'ELECTROPHYSIOLOGIE GUIDEES PAR RESONANCE MAGNETIQUE

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Detailed Description

Claims

English Abstract

A **system**, and **method** for using magnetic resonance imaging to increase the accuracy of electro-physiologic **procedures** is disclosed. The **system** in its preferred embodiment provides an invasive combined electro-physiologic, an imaging **antenna catheter** (1) which includes an RF **antenna** (3) for receiving MR signals, and diagnostic electrodes (11) for receiving electrical potentials. The combined electrophysiology, and imaging **antenna catheter** (1) is used in combination with an MR imaging scanner to guide, to provide visualization during electro-physiologic diagnostic or therapeutic **procedures**.

French Abstract

L'invention concerne un **systeme** et une **technique** qui utilisent l'imagerie par resonance magnetique pour augmenter la precision des **procedures** electrophysiologiques. Selon le mode prefere de l'invention, le **systeme** fournit un **catheter** (1) a antenne d'imagerie et

d'electrophysiologie combine invasif, comprenant une antenne RF (3...

...de resonance magnetique, et des electrodes diagnostiques (11) destinees a recevoir des potentiels electriques. Le **catheter** (1) a antenne d'imagerie et d'electrophysiologie combine est utilise en combinaison avec un dispositif de balayage d'imagerie a resonance magnetique, afin de guider et de visualiser les **procedures** therapeutiques ou diagnostiques electrophysiologiques.

#### Detailed Description

##### **SYSTEM AND METHOD FOR MAGNETIC, RESONANCE-GUIDED ELECTROPHYSIOLOGIC AND ABLATION PROCEDURES**

This application claims the benefit of U.S. Provisional Patent Application No.

60/106,965...

#### ...of the Invention

The invention relates in general to ablation and electrophysiologic diagnostic and therapeutic **procedures**, and in particular to systems and **methods** for guiding and providing visualization during such **procedures**.

#### 2. Related Art

Atrial **fibrillation** and ventricular tachyarrhythmias occurring in patients with structurally abnormal hearts are of great concern in contemporary cardiology. They represent the most frequently encountered **tachycardias**, account for the most morbidity and mortality, and, despite much progress, remain therapeutic challenges.

Atrial **fibrillation** affects a larger population than ventricular tachyarrhythmias, with a prevalence of approximately 0.5% in...

...the last 30 years, with over-2 million people in the United States affected. Atrial **fibrillation** usually accompanies disorders such as coronary heart disease, cardiomyopathies, and the postoperative state, but occurs...

...it does have a mortality twice that of control subjects. Symptoms which occur during atrial **fibrillation** result from the often rapid irregular heart rate and the loss of atrio-ventricular (AV...

...thromboembolic complications in the brain (leading to approximately 75,000 strokes per year), make atrial **fibrillation** a formidable challenge.

Two strategies have been used for medically managing patients with atrial **fibrillations**. The first involves rate control and anticoagulation, and the second involves attempts to restore and...

...up. A major disadvantage of antiarrhythmic therapy is the induction of sustained, and sometimes lethal, **arrhythmias** (proarrhythmia) in up to 10% of patients.

If sinus rhythm cannot be maintained, several approaches are used to control the ventricular response to atrial **fibrillation**. Pharmacologic agents which slow conduction through the AV node are first tried. When pharmacologic approaches...

...are not unusual, and anticoagulation cannot be used in all patients.

Medical management of atrial **fibrillation** , therefore, is inadequate.

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In addition to medical management approaches, surgical therapy of atrial **fibrillation** has also been performed. The surgical-maze **procedure** , developed by Cox, is an approach for suppressing atrial **fibrillation** while maintaining atrial functions.

This **procedure** involves creating multiple **linear** incisions in the left and right atria.

These surgical incisions create **lines** of conduction block which compartmentalize the atrium into distinct segments that remain in communication with...

...longer exists to sustain the multiple reentrant rotors, which are the basis for atrial **fibrillation** . Surgical approaches to the treatment of atrial **fibrillation** result in an efficacy of > 95% and a low incidence of complications. Despite these encouraging results, this **procedure** has not gained widespread acceptance because of the long duration of recovery and risks associated...

...of the heart (electrophysiologic studies) have also been used in the diagnosis and therapy of **arrhythmias** , and many **arrhythmias** can be cured by selective destruction of critical electrical pathways with radiofrequency ( **RF** ) **catheter ablation** . Recently, electrophysiologists have attempted to replicate the maze **procedure** using **radio - frequency catheter ablation** , where healing 20 destroys **myocardium** . The **procedure** is arduous, requiring general anesthesia and **procedure** durations often greater than 12 hours, with exposure to x-rays for over 2 hours. Some patients have sustained cerebrovascular accidents.

One of the main limitations of the **procedure** is the difficulty associated with creating and confirming the presence of continuous **linear lesions** in the atrium. If the **linear lesions** have gaps, then activation can pass through the gap and complete a reentrant circuit, thereby sustaining atrial **fibrillation** or **flutter** . This difficulty contributes significantly to the long **procedure** durations discussed above.

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Creating and confirming continuous **linear lesions** could be facilitated by improved **techniques** for imaging **lesions** created in the atria. Such an imaging **technique** may allow the **procedure** to be based purely on anatomic findings.

The major technology for guiding placement of a **catheter** is x-ray fluoroscopy. For electrophysiologic studies and ablation, frame rates of 7-15 / sec are generally used which allows an operator to see x-ray-derived shadows of the **catheters** inside the body. Since xrays traverse the body from one side to the other, all...

...body. Using one projection, therefore, it is only possible to know the position of the **catheter** perpendicular to the direction of the beam. In order to gain information about the position of the **catheter** parallel to the beam, it is necessary to use a second beam that is offset...soft tissues is not great, it is often very difficult to determine exactly where the **catheter** is within the heart. In addition, the borders of the heart are generally not accurately defined, so it is generally not

possible to know if the **catheter** has penetrated the wall of the heart.

Intracardiac ultrasound has been used to overcome deficiencies...

...possible to determine exactly where the walls of the heart are with respect to a **catheter** and the ultrasound probe, but the ultrasound probe is mobile, so there can be doubt...

...ability to accurately and reproducibly identify areas of the heart that have been ablated.

A **system** known as "non-fluoroscopic electroanatomic mapping (Ben-haim; US Patent #5391199), was developed to allow more accurate positioning of **catheters** within

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the heart. That **system** uses weak magnetic fields and a calibrated magnetic field detector to track the location of a **catheter** in 3-space. The **system** can mark the position of a **catheter**, but the **system** relies on having the heart not moving with respect to a marker on the body. The **system** does not obviate the need for initial placement using x-ray fluoroscopy, and cannot directly image ablated tissue.

MR is a known imaging **technique** which uses high-strength magnetic and electric fields to image the body. A strong static...

...static magnetic field. This frequency of precession is a natural, or resonance, frequency of the **system** (hence Magnetic Resonance Imaging).

The time-varying gradient magnetic field is used for spatial encoding of the signals from the issue. The magnitude of the gradient field is a **linear** function of the space coordinates in the magnet. As a result of the addition of...

...magnetic fields, the total local magnetic field and, thus, the local resonance frequency, becomes a **linear** function of position. Thus, imaging tissues in any plane can be accomplished because the...

...of each volume element is known in three-dimensional space.

MRI is generally considered a safe **technique**, since no x-rays are used and the electromagnetic fields do not, by themselves, cause tissue damage.

While MRI may provide the visual guidance necessary for creating and confirming linear lesions, it has been assumed that electrical wires implanted in a patient can act as **antennas** to pick up radio-frequency energy in an MR **system** and conduct that energy to the patient, thereby causing tissue injury.

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Magnetic resonance imaging has been used to guide **procedures** in which RF energy is applied to non-contractile organs such as the brain, liver...

...the heart.

U.S. Patent No. 5,323,778 to Kandarpa et al. discloses a **method** and apparatus for magnetic resonance imaging and tissue heating. There is no provision in the...

...OF THE INVENTION

It is therefore an object of the invention to provide an improved **system** and **1 5 method** for guiding and/or providing visualization during electrophysiologic **procedures**.

It is a further object of the invention to provide a **system** and **method** for guiding or visualizing ablation **procedures** which is suitable for use in the heart and other structures.

It is a further object of the invention to provide a **system** and **method** for imaging ablation **lesions** with increased resolution and reliability.

The invention provides a **system** and **method** for using magnetic resonance imaging to increase the safety and accuracy of electrophysiologic **procedures**. The **system** in its preferred embodiment provides an invasive combined electrophysiology and imaging **antenna catheter** which includes an RF **antenna** for receiving magnetic resonance signals and diagnostic electrodes for receiving electrical potentials. The  
6 combined electrophysiology and imaging **antenna catheter** is used in combination with a magnetic resonance imaging scanner to guide and provide visualization during electrophysiologic diagnostic or therapeutic **procedures**. The invention is particularly applicable to **catheter ablation** of **atrial** and **ventricular arrhythmias**. In embodiments which are useful for **catheter ablation**, the combined electrophysiology and imaging **antenna catheter** may further include an **ablation** tip, and such embodiment may be used as an intracardiac device to both deliver energy to selected areas of tissue and visualize the resulting ablation **lesions**, thereby greatly simplifying production of continuous **linear lesions**. Additionally, the ablation electrode can be used as an active tracking device that receives signal...

...for RF

therapy. The invention further includes embodiments useful for guiding electrophysiologic diagnostic and therapeutic **procedures** other than ablation. Imaging of ablation **lesions** may be further enhanced by use of MR contrast agents. The **antenna** utilized in the combined electrophysiology and imaging **catheter** for receiving MR signals is preferably of the coaxial or "loopless" type that utilizes a helical whip.

20 High-resolution images from the **antenna** may be combined with low-resolution images from surface coils of the MR scanner to produce a composite image. The invention further provides a **system** for eliminating the pickup of ...wires are detuned, by for example low-pass filters, so that they become very inefficient **antennas**. An RF filtering **system** is provided for suppressing the MR imaging signal while not attenuating the RF ablative current. Steering means may be provided for steering the invasive **catheter** under MR guidance. Lastly, the invention provides a **method** and **system** for acquisition of high-density electroanatomic data using a specially designed multi-electrode **catheter** and the NfRI scanner. This will be achieved by

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using an active tracking **system** that allows the location of each electrode to be determined.

BREEF DESCRIPTION OF THE DRAWINGS...

...of the invention.

FIG. 1 shows a schematic view of a combined electrophysiology and imaging **antenna catheter** in accordance with a preferred embodiment of the invention.

FIG. 2 shows a cross-sectional detail view of a tip portion of combined electrophysiology and imaging **antenna catheter** in accordance with a preferred embodiment of the invention.

FIG. 3 shows a block diagram illustrating the operation of an MRI scanner **system** which may be used in connection with the **system** and **method** of the invention.

FIG. 4 illustrates a schematic block diagram showing an example of radiofrequency...

...with the invention.

FIG. 5 shows a graphic representation of electrical signals measured from a **catheter** in accordance with the invention during MR imaging.

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FIG. 6 shows a high-level block diagram illustrating an ablation **system** incorporating radio-frequency filters in accordance with a preferred embodiment of the invention.

FIG. 7...

...planar  
sections.

#### DETAILED DESCRIPTION

The invention in its preferred embodiment uses MR imaging to allow **catheters** to be placed without radiation, and provides very accurate localization of **catheter** tips in 3-dimensional space. With current MRI scanners, resolution is limited by the distance...

...be present.

In accordance with a preferred embodiment of the invention, an intracardiac receiving coil/ **antenna** is used so that the receiving coil/ **antenna** is closer to the imaging volume ( **lesions** ), thereby reducing noise, increasing signal, and improving resolution where it is needed most.

In a first embodiment of the invention, MRI is used to facilitate **catheter ablation** of **atrial fibrillation** by guiding creation of continuous linear **ablation lesions** and confirming that a complete **linear lesion** has been created ( **line** of block). The visualization of areas of ablation may allow a reduction in the number of **lesions**

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needed, and may also reduce the number of recurrences, by more accurately ablating the **arrhythmias**.

FIGS. 1 and 2 show schematic and detail views, respectively, of a combined electrophysiology and imaging **antenna catheter** in accordance with a preferred embodiment of the invention. The device of the invention is...

...delivered to selected areas of tissue, the tissue imaged with an invasive (e.g., intracardiac) **antenna**, and RF **lesions** or other

targets can be visualized in both high and low resolution modes. MRI allows io visualization of **lesions** in the ventricle with the use of surface coils, and in the atria with surface coils and/or the intracardiac **catheter - antenna** . With these **catheter antennae** , the image can be aligned perpendicular to the **catheter** , such that the best resolution will be at site of the **lesion** . This **lesion** visualization can be used for (1) precise titration of therapy, (2) the ability to test the length and depth of **lesions** from new ablation-energy sources, and (3) accurate assessment of the success of making **lines** of ablation.

In addition to **catheter - antenna** , high-resolution imaging can also be done with receivers that contain loops that are...

...surface area.

MRI can also be used in accordance with the invention to guide other **procedures** .

In cardiology, accurate anatomic information, combined with electrical measurements, allows improved study of the pathophysiology of **arrhythmias** , stunning, remodeling, and **tachycardia** -induced myopathy. Outside of cardiology, it has already been demonstrated that biopsies of liver, kidney...

...could all be done safely and accurately with MR-guidance. With extensions of the biopsy **technique** , MRI-guided ablation of tumors such as metastatic liver disease,  
10  
brain tumors, and prostate...

...FIG. 2 shows a detail view of a tip portion 15 of the device. The **system** of the invention preferably comprises a combined electrophysiology and imaging **antenna catheter** 1 which is used in conjunction with an MRI scanner such that visualization can be performed simultaneously with delivery of **RF** energy to selected areas of tissue for **ablation** . In embodiments designed for **cardiac ablation** applications, the length of the io invasive portion of the device is preferably at least with electrophysiological **procedures** and testing. In embodiments useful for ablation applications, the device further includes an ablation tip...

...deflecting the tip in the appropriate direction. A connector 9 is used to interconnect the **antenna** 3 with receiver or scanner circuitry, which is discussed in further detail below, and is...

...the electrodes I 1 to external electronic devices.

The device of the invention includes an **antenna** portion 19, which may be of various suitable designs. In the preferred embodiment, a flexible, helical whip coaxial **loopless antenna** is used. Such an **antenna** can be made by removing a section of the

1 1

shield from an **antenna coaxial cable** , so as to form a 'whip' with the center conductor.

To avoid direct biofluid contact with conductive components of the **catheter** it will be covered with a non-conductive dielectric material. Addition of insulation to the **antenna** , however, increases the whip length required for optimal image quality to a length that prohibitively large for in vivo use. Incorporating a helical whip in the **loopless antenna** design overcomes this limitation by allowing up to 10 times the



electrical length to be...

...physical length as a straight conductor whip. In addition to these electromagnetic advantages, the helical **antenna** whip also improves the mechanical properties of the device and thereby greatly improve intravascular and intracardiac navigation of the **catheter** without kinking, folding or mechanical failure of the whip. The flexible helical whip has **guidewire** properties and thus reduces the risks of vascular or or cardiac perforation. The length of helical whip can be varied to help in tuning the **antenna** to the optimal impedance and in optimizing the signal-to-noise ratio. Further details regarding the structure and design of suitable **loopless antennas** can be found in U.S. Patent No. 5,928,145, issued July 27, 1999, the entire disclosure of which is incorporated herein by reference.

Since **loops** can receive more signal in a given imaging volume, an **antenna** incorporating a **loop** may provide an improved signal-to-noise ratio, resulting in clearer images. A **loop** can be formed, where the **antenna** whip 21 is connected to the **antenna** body 19 via a miniature capacitor. A balloon can be incorporated into the **catheter**, and the loop can be attached to the surface of the balloon. When the balloon is inflated, the loop will expand.

In embodiments of the invention wherein a coaxial **loopless antenna** is utilized, a helical whip portion 21 of the flexible **antenna** protrudes from the distal tip to complete the dipole **antenna**. The whip portion 21 is coated with an insulating layer and its tip 23 can...

...a "J" to help prevent the whip from perforating

1 2

internal physiological structures. The **antenna** whip portion 21 should be insulated from the ablation tip.

When the device of the invention is used for intracardiac ablation **procedures**, tissue is imaged with the **antenna** and RF **lesions** can be visualized in both high and low resolution modes. As is discussed in detail...

...enhanced with MRI contrast, such as gadolinium. Software can be provided for optimally visualizing the **lesions**, and for allowing the operator to change viewing perspective in near-real time.

10

As is set forth above, embodiments of the invention which are useful for ablation **procedures** preferably include an ablation tip 13. As an alternative to the preferred embodiment wherein the active element of the **antenna** runs within the **catheter** in a coaxial fashion, the RF ablation element in the ablation tip may be designed...

...for MR imaging. In such embodiments, a switching device can be used to switch the **catheter** between imaging and ablation modes. When not in ablation mode, the ablation electrode, and the other electrodes on the **catheter**, can be used to measure electrical signals.

Another embodiment of the combined **antenna** and RIF probe device is the use of untuned RIF electrodes as tracking devices. Single...

...generation of true electroanatomic data.

1 3

For most applications, the impedance of the imaging **antenna** must match

the impedance of the input amplifier. With an ordinary 64 MHz input amplifier...

...an appropriate value. A network analyzer can be used to allow optimal matching of different **antenna** designs. o customize matching to an individual patient, the network analyzer can be automated and incorporated into the matching network to automatically tune the matching network after the **antenna** has been placed into the patient.

The **catheter antenna** device of the invention in accordance with its preferred embodiment is constructed so as to...

...2) the MRI electromagnetic fields do not alter the normal functioning of the device; (3) **cardiac** arrhythmias are not produced by the device, and (4) no damage to the tissue is produced by **radio - frequency** energy received from the MRI scanner. The presence of ...the images.

FIG. 3 shows a block diagram illustrating the operation of an MRI scanner **system** which may be used in connection with the **system** and **method** of the invention.

A magnet is provided for creating the magnetic field necessary for inducing...

...for protecting electronic equipment (e.g., the MR scanner) from RF produced by the ablation **system**, for protecting the ablation and measuring **system** from RF produced by the MR scanner, and for allowing measurement of the relevant electrical signals. Without adequate radio-frequency filters, the electronics attached to the **catheter** may malfunction during imaging. FIG. 4 illustrates a schematic block diagram showing an example of...

...C1, C3; and L2, L4, C2, C4), is preferably placed in each wire to the **catheter**. These filters can reduce the 15 - 32 volts of radio-frequency pickup down to a...

...noise was not rejected by the RF filters. This filter arrangement is used in the **catheter** -intracardiac electrogram measuring circuit. The circuit for ablation does not incorporate the active filters, since while the RF filtering **system** is designed to suppress the 64MHz imaging signal. It does not attenuate the RF ablative current, since the radio frequency of the ablation **system** is 200-800 kHz, and the corner for the lowpass RF filters is 1-10...

...to measure electrograms.

FIG. 5 shows a graphic representation of electrical signals measured from a **catheter** in accordance with the invention during MR imaging. FIG. 5(a) shows the signals measured from a **catheter** without the use of RF filters; it can be seen that the ECG is obscured...

...frequency interference is removed and an ECG signal is now apparent. The pairs of vertical **lines** are artifacts from the gradient fields. FIG. 5(c) shows such signals wherein active RF...

...artifact is also suppressed.

FIG. 6 shows a high-level block diagram illustrating an ablation **system** incorporating the filters described above. The RF Generator may comprise, e.g., a standard clinically...

...250 Q load. The output frequency from the RF generator is directed to the ablation **catheter** through two filter assemblies (low pass, 2Mhz comer). Both filter assemblies are fully shielded and...

...defibrillator (identified as "defib" in FIG. 8) may comprise a standard defibrillator used in ablation **procedures** .

1 6

It is important that the location of the tip of the **catheter** can be accurately determined. A number of modes of localization can be used. Because the **catheter** is a receiver it can be used to directly image the tissue around it. This outside the body. The location of the **catheter** in the body can be tracked by the bright **line** of signal moving in the scout image. The scout image can be updated at an...

...motion. An interactive control will allow the physician to io "zoom in" towards the bright **catheter** , finally resulting in a high resolution image around the **catheter** tip. The "zoom" function can be achieved with interactive control of the imaging gradients.

A...

...of the heart can be updated after each ablation and displayed with an appropriate rendering **technique** .

The guidance of the **catheter** tip to the next site of ablation, or to fill in a previous ablation **line** can be assisted using the MR images. This assistance can be entirely passive, in that the physician uses the images to manipulate the **catheter** , or automatic tracking and feedback could assist that physician to steer the **catheter** .

The **lesions** may be visualized using standard imaging **techniques** . It may be necessary to MR contrast to enhance the **lesions** to allow adequate visualization to occur. One such enhancement **method** uses gadolinium-DTPA, but other suitable contrast agent could be used. The rationale underlying the utilization of gadoliniumDTPA based contrast agents to enhance signal intensity in **atrial** or **ventricular**

1 7

**myocardium** injured by **RF** during therapeutic **ablation** is based on the following observations: 1) Gadolinium-DTPA exerts its signal enhancing effect by...

...penetrate the uninjured cell membrane and is therefore restricted to the extracellular space in uninjured **myocardium** . After the **RF** bum, the injured membrane allows penetration of the contrast agent thus increasing significantly the volume...

...spatial resolution than in non-enhanced images.

Gadolinium-DTPA can be injected prior to the **RF** **ablation** protocol to enhance injured **myocardiurn** as the **lesions** are produced. The agent takes 5-10 minutes to equilibrate between extracellular and intracellular spaces...

...does not cause side effects leading to discomfort or complications in patients.

Imaging of ablated **lesions** may be further enhanced by use of thermal imaging **techniques** . Thermal imaging can be accomplished by using phase differences in MR signals.

Three-dimensional image reconstruction can be performed using the **system**

and **method** of the invention. FIG. 7 shows three-dimensional reconstructions of MR images from planar sections...

...the spread of mechanical activation as the wave of electrical activation spreads across the left **ventricle** from the right **ventricular** pacing site. Similar image processing **techniques** can be used for visualizing **ablated** areas

The advantages of the **system** and **method** for MR-guided electrophysiology in accordance with the invention will now be discussed in further...

...resulting 2dimensional image sequence can serve as an effective substitute for x-ray fluoroscopy. The **system** can thus facilitate **catheter** placement for EP study with real-time imaging, without the need for ionizing radiation. **Catheters** used in this **system** must be composed entirely of non-ferromagnetic materials, so as not to perturb the electromagnetic...

...free MR imaging.

MRI allows for precise localization of object elements in three-dimensional space. **Catheter** tip position within the heart can thus be determined accurately and precisely, and can then...

...not possible with x-ray fluoroscopy.

Electrical activation timing information obtained via an EP mapping **catheter**, when combined with **catheter** localization information, enables accurate color-coded activation maps. This capability is most useful in determining the site of origin of an atrial or ventricular **tachycardia**.

19

Activation maps can be superimposed on anatomically accurate reconstructions of cardiac structure. Spatially...

...voltage data, however, requires knowledge of the location of each electrode in contact with the **myocardium**. This can be achieved by using high-density basket **catheter** electrodes in conjunction with active tracking **RF** coils. Each untuned electrode is capable of receiving signal, which in turn, provides the 3...

...anatomic structures.

This provides significant advantages beyond the capabilities of the non-fluoroscopic electroanatomic mapping **system** noted above, since that **system** does not provide accurate anatomic information, again without additional hardware.

An imaging **antenna** can be incorporated into a steerable mapping/ablation

**catheter**, enabling high-resolution imaging in the region near the **catheter** tip. The image obtained with this **antenna** has a similar radius of view as that with intracardiac ultrasound, but ...Furthermore, this high-resolution image is obtained without the need for placement of an additional **catheter**, as is required with intracardiac ultrasound.

High-resolution images derived from the internal **antenna** can be combined with lower-resolution wide-field images obtained with the external coil into a single image.

This composite image will display the entire **cardiac** cross section with enhanced

resolution in the area of greatest interest

When the **ablation** /imaging **catheter** is used for the delivery of ablative radiofrequency energy, the high-resolution image obtained via this **catheter** enables visualization of the **lesion** and of **lesion** growth. It may also be possible to visualize **lesions** with surface coils alone, if the tissue is thick enough.

2 0

Directional orientation, as well as location, of the **catheter** tip can be determined in three-dimensional space. The high-resolution image data obtained via the internal **antenna** can be displayed in any plane, and in particular, in the plane orthogonal to the **catheter**. Since the image is obtained with the same **catheter** that is delivering the ablative energy, the orthogonal-plane image is guaranteed to display the **lesion** at its maximal radius, without the need to manipulate a second (imaging) **catheter** into alignment with the ablation **catheter**. **Lesion** size will thus not be underestimated as often occurs with intracardiac ultrasound. In the latter case, the imaging **catheter** differs from the ablation **catheter**. It is therefore not necessarily imaging at the same io level as the ablation **catheter** tip, and is not necessarily parallel to the ablation **catheter** so the image plane is oblique to the **lesion** equator.

MR is an imaging modality that can be tuned to characterize tissue physiology as well as structure. This enables imaging of **lesions** by virtue of changes in structure and cell function that occur with fulguration. Injection of gadolinium further enhances the MR image contrast between healthy and **ablated myocardium**. Intracardiac ultrasound, on the other hand, enables visualization of **lesions** only to the extent that tissue echogenicity is altered.

Because the MRI-guided EP **system** of the invention combines two-dimensional real-time image sequences, accurate three-dimensional **catheter** tip localization for activation mapping, and the ability to "see" myocardial tissue and **lesion** growth, it offers the best features of x-ray fluoroscopy, the non-fluoroscopic electroanatomic mapping **system**, and intracardiac ultrasound all at once without ionizing radiation, extra venipunctures, or excessively expensive **catheters**. High-resolution visualization of ablative **lesions** by the internal MR **antenna** allows for documentation of whether or not RF application resulted in successful **lesion**

2 1

development and of where **lesions** have and have not yet been made. This facilitates efficient **catheter** placement so that RF is applied only to tissue not previously **ablated**.

The high-resolution images obtained with the internal MR **antenna** enables

visualization of the relatively thin **atrial** wall. This structure may not be well visualized by the external MR coil due to...

...and images discussed above makes high-resolution MRI guidance ideal for visualization and verification of **ablative** lesion lines, particularly in **atrial** tissue. This is useful for **ablation** of the reentrant circuit in typical **atrial flutter** and is crucial for successful **ablation** of **atrial fibrillation**.

Investigators have shown that **atrial fibrillation** can be eliminated with multiple lines of **ablative** lesions placed in the right and left **atria** to emulate the surgical maze **procedure**. Failures of the 'percutaneous maze' **procedure** have resulted primarily from incomplete **lesion lines**. MRI guidance should allow rapid confirmation of **lesion line** continuity and avoidance of unnecessary repetition of RF application where tissue has **2o** already been successfully **ablated**.

The MRI-guided **catheter ablation system** offers advantages in **ablation** of ischemic and idiopathic **ventricular tachycardias**, ectopic **atrial tachycardias**, **atrial flutter**, and **atrial fibrillation**. Unlike AV node reentry and accessory pathway mediated **tachycardia**, these other **arrhythmias** have lower **ablation** success rates and longer **ablation procedure** durations, primarily due to difficulties in accurate activation mapping or confirmation of **lesion** development with conventional equipment.

**Procedure** durations and risk of complications should thus be reduced substantially with the MRI-guided **catheter ablation system**.

22

While the invention has been particularly shown and described with reference to a preferred...

#### Claim

I 1. A **method** for performing an electrophysiological **procedure**, comprising the steps

Of:

placing a subject in a main magnetic field;  
introducing an MR-compatible electrode **catheter** ;  
acquiring a magnetic resonance signal;  
using magnetic resonance imaging to determine the location of said MR compatible electrode **catheter** ; and,  
using said MR-compatible electrode **catheter** to acquire electrical signals indicative of an electrophysiological state. i 2. The **method** according to claim 1, wherein said electrical signals indicative of an electrophysiological state comprise intracardiac electrograms. i 3. The **method** according to claim 1, wherein said MR-compatible electrode **catheter** includes a tip comprising gold.

4 The **method** according to claim 1, wherein said MR-compatible electrode **catheter** comprises an MR-visible material. i 5. The **method** according to claim 3, wherein said MR-visible material comprises a Metal.

2 4

i 6. The **method** according to claim 1, further comprising using a magnetic resonance contrast agent to enhance images...

...step of using magnetic resonance imaging to determine the location of said MR-compatible electrode **catheter**. i 7. The **method** according to claim 1, wherein said step of acquiring a magnetic resonance signal comprises the step of using a magnetic resonance imaging **antenna** which is integral with said MR-compatible electrode **catheter**.

i 8. A **method** for treating **cardiac arrhythmias**, comprising the steps of:

placing a subject in a main magnetic field;  
introducing an **ablation catheter** ; and,  
using magnetic resonance imaging to visualize ablation **lesions** created

using said ablation **catheter** . I 9. The **method** according to claim 8, wherein said step of using magnetic resonance imaging comprises the step of using a **catheter antenna** to receive magnetic resonance signals.

10 The **method** according to claim 9, wherein said **catheter antenna** comprises a **loopless antenna** .

11 The **method** according to claim 9, wherein said **catheter antenna** comprises a **loop antenna** .

25

12 The **method** according to claim 8, further comprising the step of using a magnetic resonance contrast agent to enhance the visibility of said ablation **lesions** in MR images.

13 The **method** according to claim 12, wherein said step of using a magnetic resonance contrast agent comprises the step of using gadolinium-DTPA.

14 A **system** for performing ablation therapy, comprising:  
ablation tip means for applying ablative energy to create ablation **lesions** ; **catheter** means for inserting said diagnostic electrodes into a region to be treated;  
magnetic resonance **antenna** means, integral with said **catheter** means, for receiving magnetic resonance signals; and,  
means for analyzing said received magnetic resonance signals...

...said means for inserting can be guided to said region to be treated.

15 The **system** for performing ablation therapy according to claim 14, further comprising:  
a plurality of diagnostic electrodes.

16 The **system** for performing ablation therapy according to claim 14, wherein said magnetic resonance **antenna** means comprises a **loopless antenna** .

2 6

17 A **system** for magnetic resonance imaging-guided **catheter** ablation, comprising:  
means for generating RF ablation current;  
means for generating an RF magnetic resonance...

...filter means for filtering said first frequency range from said RF ablation current.

18 The **system** according to claim 17, further comprising magnetic resonance **antenna** means for receiving induced magnetic resonance signals.

19 The **system** according to claim 18, wherein said magnetic resonance **antenna** means comprises an invasive **catheter antenna** .

20 The **system** according to claim 19, wherein said invasive **catheter antenna** comprises a **loopless antenna** . i 21. The **system** according to claim 17, wherein said means for generating a RF magnetic resonance imaging signal...

...means comprises means for filtering said resonance signal from said

ablation signal.

27

22 The **system** according to claim 17, wherein said filter means comprises a lowpass filter. i 23. The **system** according to claim 17, wherein said filter means comprises a multistage filter. i 24. The **system** according to claim 17, wherein said filter means comprises means for filtering gradient-induced noise.

25 The **system** according to claim 24, wherein said means for filtering gradient-induced noise comprises a series of active filters which filter a different frequency range than the RF filters.

26 A **method** for performing an electrophysiological **procedure**, comprising the steps of:  
placing a subject in a main magnetic field;  
introducing an invasive imaging **antenna** or coil;  
acquiring a first magnetic resonance image from said invasive imaging **antenna** or coil;  
acquiring a second magnetic resonance image from a surface coil;  
combining said first...

...images to produce a composite image; and,  
using said composite image to guide said electrophysiological **procedure**

I 1

2 8

27 The **method** according to claim 26, wherein said step of using said composite image to guide said electrophysiological **procedure** comprises the step of using said composite image to guide an ablation **procedure** ..

28 The **method** according to claim 26, further comprising the step of using said composite image to construct...

...three-dimensional map of areas in the heart that have undergone ablation. i 29. The **method** according to claim 26, further comprising the step of using said composite image to construct a three-dimensional rendering of the heart. i 30. The **method** according to claim 29, further comprising the step of storing said three-dimensional rendering into a texture map of an imaging volume.

31 A **system** for magnetic resonance imaging-guided **catheter** ablation, comprising:  
electrode means for receiving electrical signals indicative of an electrophysiological state, said electrical...

...a first frequency range;  
means for generating an RF magnetic-resonance-inducing signal;  
magnetic resonance **antenna** means for receiving magnetic resonance signals  
from a region to be treated;  
filter means for...

...frequency range from said RF magneticresonance-inducing signal.  
i 32. A combined electrophysiology and imaging **catheter**, comprising:

29

at least one diagnostic electrode;



**catheter** for inserting said diagnostic electrode into a region to be studied; and,  
an invasive magnetic resonance **antenna** , integral with said **catheter** ,  
for  
receiving magnetic resonance signals.

33 The combined electrophysiology and imaging **catheter** according to claim 32,  
further comprising:  
steering device for deflecting said **catheter** , whereby said **catheter**  
can be steered to said region to be studied. i 34. The combined  
electrophysiology and imaging **catheter** according to claim 33, wherein  
said steering device comprises a steering wire. i 35. The combined  
electrophysiology and imaging **catheter** according to claim 34, wherein  
said steering wire is of a titanium construction. i 36. The combined  
electrophysiology and imaging **catheter** according to claim 35, wherein  
said steering wire is housed in a sheath. i 37. The combined  
electrophysiology and imaging **catheter** according to claim 33, wherein  
said steering device comprises a steering knob. i 38. The combined  
electrophysiology and imaging **catheter** according to claim 37,  
3 0

wherein said steering knob is operable to move a steering wire toward or  
away from a distal tip of said **catheter** . i 39. The combined  
electrophysiology and imaging **catheter** according to claim 32,  
further comprising:  
an ablation tip for applying ablative energy to a region to be treated. i  
40. The combined electrophysiology and imaging **catheter** according to  
claim 32,  
further comprising:  
a flexible **antenna** whip at a distal portion of said **catheter** . i 41.  
The combined electrophysiology and imaging **catheter** according to claim  
40, wherein said flexible **antenna** whip is coated with an insulating  
layer. i 42. The combined electrophysiology and imaging **catheter**  
according to claim 40, wherein said flexible **antenna** whip comprises a  
tip which is formed into a J-shape to prevent perforation. i 43. The  
combined electrophysiology and imaging **catheter** according to claim 32,  
wherein said **catheter** and all components housed therein are fabricated  
of materials having low-magnetic susceptibility.

44 The combined electrophysiology and imaging **catheter** according to  
claim 32,  
3 1

further comprising a tip which is at least 4 millimeters in length and  
suitable for use in RF ablation **procedures** . i 45. The combined  
electrophysiology and imaging **catheter** . according to claim 44, wherein  
said tip is fabricated from platinum. i 46. The **system** for performing  
ablation therapy according to claim 14, wherein said magnetic resonance  
**antenna** means comprises a **loop antenna** . i 47. The **system** according  
to claim 24, wherein said means for filtering gradientinduced noise  
comprises a series of...

...filter a different frequency range than the RF filters.

48 The combined electrophysiology and imaging **catheter** according to  
claim 34, wherein said steering wire is of a non-magnetic construction. i  
49. The combined electrophysiology and imaging **catheter** according to  
claim 44, wherein said tip is fabricated from gold.

22/3,K/54 (Item 54 from file: 349)  
DIALOG(R) File 349:PCT FULLTEXT  
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00513167 \*\*Image available\*\*

**TISSUE ABLATION SYSTEM AND METHOD FOR FORMING LONG LINEAR LESION**  
**SYSTEME ET PROCEDE D'ABLATION TISSULAIRE PERMETTANT D'OBTENIR UNE LESION**

**LINEAIRE LONGUE**

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Detailed Description

Claims

Detailed Description

... been developed.

These less invasive catheter-based therapies generally involve introducing a catheter within a **cardiac** chamber, such as in a percutaneous transluminal **procedure**, wherein an energy sink on the cathetees distal end portion is positioned at or 0...

...subdivided into two related categories, based an the etiology of the atria[ arrhythmia. First, focal **arrhythmia** 's have proven amenable to localized **ablation techniques**, which target the foci of aberrant electrical activity. Accordingly, devices and **techniques** have been disclosed which use end-electrode **catheter** designs for ablating focal **arrhythmia** 's centered in the pulmonary veins, using a point source of energy to ablate the locus of abnormal electrical activity. Such **procedures** typically employ incremental application of electrical energy to the tissue to form focal **lesions**. The second category of **catheter**-based ablation methods are designed for treatment of the more common forms of atrial fibrillation, resulting from perpetually wandering reentrant wavelets. Such arrhythmia's are generally not amenable to localized **ablation techniques**, because the excitation waves may circumnavigate a focal **lesion**. Thus, the second class of **catheter**-based approaches have generally attempted to mimic the earlier surgical segmentation **techniques**, such as the maze **procedure**, wherein continuous **linear lesions** am required to completely segment the **atrial** tissue so as to block conduction of the reentrant wave fronts.

= (US) 6527769

See  
claim 10,  
"US"  
version

An example of an **ablation method** targeting focal **arrhythmia** 's originating from a pulmonary vein is disclosed by Haissaguerre et al. in 'Right and Left Atrial Radiofrequency Catheter Therapy of Paroxysmal Atrial Fibrillation' in Joumal of CardiovascLiarElectmphysiology7(12),pp 1144(1996). Haissaguerreetal.descfiberadofrequencycatheterabla6onof drug-refractory paroxysmal **atrial** fibrillation using linear **atria** [ lesions complemented by focal **ablation** targeted at **arrhythmogenic** foci in a screened patent population. The site of the **arrhythmagenic** foci were generally located just inside the superior pulmonary vein, and were allsted using a standard 4 mm tip single ablation electrode.

Another ablation **method** directed at **paroxysmal arrhythmia** 's arising from a focal source is disclosed by Jais et al. 'A focal source treated by discrete radiofrequency ablation' Ciredadon 95:572-576 (1997). At the site of **arrhythmogenic** tissue, in both fight and left **atria** , several pulses of a discrete source of railofrequency energy were applied in order to eliminate the **fibrillatory process** .

Application of **catheter** -based ablation **techniques** for treatment of reentrant wavelet **arrhythmia** 's demanded development of **methods** and devices for generating continuous **linear lesions** , like those employed in the maze **procedure** .

Initially, conventional ablation tip electrodes were adapted for use in 'drag bum' **procedures** to form **linear lesions** . During the SUBSTITUTE SHEET (RULE 26)

"drag" **procedure** , as energy was being applied, the **catheter** tip was drawn across the tissue along a predetermined pathway within the heart. Alternatively, **lines** of ablation were also made by sequentially positioning the distal tip electrode, applying a pulse of energy, and then re-positoring the electrode along a predeten-nined **linear** pathway.

Subsequently, conventional **catheters** were modified to include multiple electrode arrangements. Such **catheters** typically contained a plurality of ring electrodes circling the **catheter** at various distances extending proximally from the distal tip of the **catheter** .

While feasible **catheter** designs existed for imparting **linear** ablation tracks, as a practical matter, most of these **catheter** assemblies have been difficult to position and maintain placement and contact pressure long enough and in a sufficiently precise manner in the beating heart to successfully form segmented **linear lesions** along a chamber wall. Indeed, many of the aforementioned **methods** have generally failed to produce closed transmural **lesions** , thus leaving the opportunity for the reentrant circuits to reappear in the gaps remaining between...

...drag ablations. In addition, minimal means have been disclosed in these embodiments for steering the **catheters** to anatomic sites of interest such as the pulmonary veins.

Subsequently, a number of solutions to the problems encountered with precise positioning, maintenance of contact pressure, and **catheter** steering have been described. These include primarily the use of (1) preshaped ablating configurations, (2) 1 5 deflectable **catheter** assemblies, and (3) transcatheter ablation assemblies.

One approach to improved placement has been to use preshaped configurations which impart various predetermined **lesion** patterns, such as 'hairpins' or 'J-shapes". Typically, these configurations are situated

at the distal end of various steering **catheters** . Such **catheters** generally include steering wires, extending from a steering mechanism at the proximal end of the **catheter** to an anchor point at the distal end of the **catheter** . By applying tension to the steering wires, the tip of the **catheter** can be directed in a desired direction. Furthermore, some **catheters** comprise a rotatable steering feature which allows the **catheter** as a whole to be rotated about its longitudinal axis, by manipulating the proximal end of the **catheter** . This exerts a torque which translates to a rotating motion at the distal end which allows a laterally deflected distal tip to be rotated. Once the **catheter** is steered and positioned to a desired site within an **atria** [ chamber, **ablating** elements may be activated to form the **lesion** .

Some preshaped **catheter** assemblies employ ...a flexible outer sheath which is advanced over the distal end of the preshaped 'guide' **catheter** . Movement of the guide **catheter** within the sheath modifies the predetermined curve of the distal end of the **catheter** . By inserting different shaped guide **catheters** through the outer sheath, different shapes for the distal end of the **catheter** are created. In one embodiment, the guide **catheter** position is visualized by X-ray fluoroscopy and progressively repositioned in real time by remote...

...along a preferred pathway in the moving wall of a beating atrium to form continuous **lesions** .

Deflectable **catheter** configurations adapted to form **curvilinear lesions** within an atrial chamber, include devices having a three dimensional basket structure that encloses an...

...basket elements may carry single or multiple electrodes. The baskets may be deployed from the **catheter** by removal of a sheath, done by manipulating the steering assembly located at the proximal end of the **catheter** . Such deflectable **catheter** assemblies may form elongated **lesions** , or simple or complex patterns of **curvilinear lesions** , depending on the pattern of ablating

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electrodes on the basket elements. **Curvilinear** elements may be deployed individually in succession to create the desired maze pattern. In further embodiments, **curvilinear** elements may include a family of flexible, elongated ablating elements which are controlled by...

...mechanism thereby permitting the physician to create flexes or curves in the ablating elements. Such **curvilinear** elements include a variety of ablating electrode configurations including **linear** ribbons and closely wound spirals. A further variation includes the use of gripping members which serve to fix the position of the **ablation** surface against the atrial wall. The gripping members may include teeth or pins to enhance...

...maintaining a substantially constant pressure against the heart tissue to increase the uniformity of the **ablation** .

Transcatheter-based assemblies include systems for creating both **linear lesions** of variable length or complex **lesion** patterns. Such assemblies and **methods** involve **catheter** systems which can adapt to the tissue structures and maintain adequate contact and which are easily deployable and maneuverable. One example of a transcatheter-based assembly and **method** for creating complex **lesion** patterns includes the use of flexible electrode segments with an adjustable coil length which may...

...a composite structure which may be flexed along its length to form a variety of **curvilinear** shapes from a generally **linear** shape.

Other transcatheter **ablation** assemblies include the use of steerable vascular catheters which are expanded to conform to the surface of the **cardiac** chamber. One such expandable **system** comprises single or multiple proximally constrained diverging splines which expand upon emergence from the distal end of a **catheter** sheath, like the deflectable basket assembly described above. The splines are sufficiently rigid to maintain expandable multi-electrode **catheter** is adapted to be positioned against the inner wall of a cardiac chamber to create linear continuous lesions.

Another example describes an expandable structure and method for **ablating cardiac** tissue, including a bendable probe which is deployed within the heart. The probe carries at least one elongated flexible **ablation** element, a movable spline leg and further including a bendable stylet in a single loop...

...provides for tension to bend the stylet which then flexes the ablation element into a **curvilinear** shape or other readily controlled arcuate **catheter** shapes to allow a close degree of contact between the electrode elements and the target tissue for forming long, thin **lesion** patterns in cardiac tissue.

An additional example of a bendable transcatheter assembly comprises an outer delivery sheath and an elongated EP device slideably disposed within the inner **lumen** of the delivery sheath and secured at its distal end within the delivery sheath.

The...

...the distal section of the delivery sheath which engages the heart chamber, thereby forming a **linear lesion** in **atrial** wall.

None of the present catheter-based devices, however, include a tissue **ablation** assembly having two separate and independent delivery members with an elongated ablation member coupled therebetween...

...extending between the first and second delivery members. Nor does the prior art disclose a **method** for securing the ablation member between a first and second 4

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anchor, thereby maintaining a desired **linear** position in contact with the atrial wall and facilitating the formation of a **linear ablation** track along the length of tissue between the anchors.

#### Summary of the Invention

A tissue...the first delivery member is adapted to controllably position the first end portion of the **ablation** member within the atrium and to secure the **ablation** element to the first predetermined location. Similarly, by manipulating the proximal end portion of the...one further aspect of the modes just described, a tracking member for tracking over a **guidewire** or other guidemember is included with the first or second delivery member, or the first...

...ablation assembly of the present invention.

Figure 7A is a perspective view of another tissue **ablation** assembly in

accordance with the present invention, illustrating delivery through a transeptal sheath in a transeptal left atria[ **ablation procedure** .

SUBSTITUTE SHEET (...C schematically show two alternative cross-sectional shapes for the delivery members of the tissue **ablation** assembly shown in Figure 7A.

Figure 7D shows a cross sectional view of a left **atrial** delivery **catheter** having first and second passageways which are separated by a deflectable wall, and shows in...

...separated by the wall.

Figure 7E shows a similar cross-sectional view of a left **atrial** delivery catheter and tissue **ablation** device assembly as shown in Figure 7D, although showing one mode of operation wherein the wall is deflected to one side of the delivery **catheter** and an ablation member is shown in shadowed view to extend between the first and...

...7E, and shows a different made for the wall as it deflects within the delivery **catheter** to allow the ablation member to bridge between the first and second passageways.

Figure 7G...

...assembly shown in Figure 11A, illustrating the assembly during use in forming a **lesion** from a lower pulmonary vein to a **mitral** valve annulus.

Figure 12 shows a perspective view of a tissue **ablation** assembly similar to that shown in Figure 10C, except further including a circumferential ablation member in combination with a **linear** ablation member in an overall **catheter** assembly.

Figure 13A shows a sectioned cross-sectional view of a circumferential ablation member an...

...T

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Figure 13B shows a transverse cross-sectional view taken along line 11313-11313 through the elongate body of the delivery member shown in Figure 13A.

Figure 13C shows a transverse cross-sectional view taken along line 13C-13C through the circumferential ablation element along the circumferential ablation member shown in Figure...

...as through an ostium of a vessel extending from the wall, for example, including a **guidewire** engaging or tracking member which provides a bore or lumen adapted to track a **guidewire** through an ostium of a **lumen** extending from the body space wall.

Furthermore, an expandable element, such as an expandable balloon...

...also be used in addition or in the alternative to that particular element.

The term '**guidewire**' as used herein will be understood by those of skill in the art to cover any member which serves as a guide, including but not limited to a conventional **guidewire**, a **catheter**, a deflectable tip **catheter**, such as the type with distal end electrodes for mapping, as well as a hollow guide **tube**.

The term 'ablation' or derivatives thereof is ...of the tissue properties to substantially block conduction of electrical signals from or through the **ablated** cardiac tissue.

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The term 'element' within the context of ' **ablation** element' is herein intended to mean a discrete element, such as an electrode, or a...

...current (DC) or alternating current (AC) source, such as a radiofrequency (RF) current source; an **antenna** element which is energized by a microwave energy source; a heating element, such as a... beneficial mode of the invention, which mode is specifically adapted for use in the left **atrium** of a mammal. In this mode, the elongate ablation element is adapted to have its...

...in substantial contact with the tissue that spans the length between those ostia. By subsequent **ablation** of the tissue between anchors in the adjacent ostia, a long **linear lesion** is created and provides a conduction block to electrical flow across the length of the **lesion**.

As will be appreciated from the more detailed disclosure of the embodiments below, a pattern of multiple long **linear lesions** between adjacent pulmonary vein ostia, and also including portions of the **mitral** valve annulus and septum, may be completed with the present invention. One pattern of such multiple **ablation lesions** can be considered a 'box'

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of isolated conduction within the region...

...to provide a less-invasive improvement and less traumatic alternative to the invasive 'maze' surgical **procedure** previously described.

#### Tissue Ablation Assemblies

While a number of embodiments of the present invention are...detail to the design for first delivery member (110), as shown in Figure 1A, a **guidewire** tracking member (134) is tubular and includes a **guidewire lumen** or passageway (136) between a distal guidewire port (138) and a proximal guidewire tubular and includes a **lumen** or passageway (148) that is slideably engaged over a guide member (150).

The guide member...

...various features of the Figure 1A embodiment are believed to provide beneficial functionality in **ablating** a length of tissue between adjacent vessels, such as between pulmonary vein ostia in the left **atrium**.

In one example of the functional aspects of the design shown in Figure 1A, both...

...the delivery member (110) is adapted to controllably position the respectively engaged portions of **ablation** member (114) within an **atrium**. More specifically, the first delivery member (110) is adapted to track over guidewire (140) in order to advance or withdraw from a pulmonary vein which is engaged by the **guidewire**. Consequently, the first delivery member is adapted to controllably place and remove the ablation element...

...of ablation member (114) within an adjacent pulmonary vein. However, in contrast to the " **guide wire** tracking' mechanism provided by the first

delivery member 11 10), the second delivery member (1...of the delivery members to be seated deeply within a pulmonary vein while allowing each **ablation** member end to extend proximally out of the respective vein in order to traverse the adjoining region of atrial wall tissue. Moreover, the hinge point (144) for the 1 0 **ablation** member and at least one of the delivery members also allows the assembly to 'collapse...pulmonary vein, the ablation member (11 14) is adapted to compress against the region of **atrial** wall tissue between the veins. It is believed that this compression may deflect the curved shape of **ablation** membpr(114) against a bias force along that curve and thereby provide a means for transmitting...provided by the other respectively coupled members, as is shown in Figure 2B. In one **method** of making this transition, the wall forming the **lumen** is collapsed over the coupling member's arm, such as by heat shrinking the respective **tubing** over the coupling member's arm. Alternatively, an outer jacket (not shown) may be placed...

...that jacket. In addition, or in the alternative to both or either of these other **methods**, an adhesive may be used to pat the coupling member to the delivery and ablation...

...variation, a composite member may be used, such as for example a coil reinforced polymeric **tubing**, at the transition to form the hinge point (244). Moreover, notwithstanding the particular variations just...

...engagement of the tip of the delivery member deep within a vessel such that the **ablation** member extends proximally therefrom so that it may engage the length of atrial wall tissue extending from the vein for **ablation**.

In one further beneficial aspect of the embodiment shown for delivery members (210,212) in...

...body of the type shown for each delivery member may allow for additional passageways or **lumens** besides just the guidewire **lumens**, which additional passageways may further allow for additional components along the devices which may further facilitate the ablation **process**. For example, passageways (236,248) are shown in shadow along first and second delivery members actuator.

In addition, each of the **guidewire** tracking members (234,246) shown in Figure 2A, and also shown previously 0 34) for...

...first delivery member in Figure 1 A and B, is adapted to receive the respective **guidewire** through its **lumen** such that the guidewire extends externally of the **catheters** elongate body on either side of the region of slideable engagement. This arrangement, however, is...

...a sufficient variation. Or, a suitable strand of material for forming a looped bore for **guidewire** engagement may also be constructed out of a filament fiber, such as a Kevlar or nylon filament fiber. One more specific example of such an alternative **guidewire** tracking member which may be suitable for use in the current invention, particularly as a distal **guidewire** tracking member, is disclosed in U.S. Patent No. 5,750,702 to Amoy.

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...to Figure 3, first delivery member (310) has an elongate body (309) which forms a **guidewire** tracking member that includes a guidewire lumen or passageway (336) extending between a distal guidewire... and a proximal port (not shown). A first guidewire (340) is slideably



engaged within the **guidewire** passageway (336). A second passageway (376) also extends along the elongate body (309) between a...believed that this arrangement beneficially allows for a variable distance between the anchors formed by **guidewire** tracking members. In addition, it has been observed that, by pulling on the first end...first and second delivery members (610,612) with guidewire tracking members (634,646) engaged over **guidewires** (640,650), and further provides dual-coaxial engagement within those delivery members (610,612) with...6, the first and second anchors (684,686) provided in part by the two elongate **guidewire** tracking members (634,646) of the delivery members (610,612) may further include expandable members...

...to be particularly well suited to this design by virtue of the extensions of the **guidewire** tracking members distally beyond the ablation member.

In an alternative variation not shown, it is...

...by reference to Figure 5, except that the distal end portions of the respective delivery **catheters** have curved shapes. These shaped regions (711,713) are adapted to point the first and...

...712) in a round delivery sheath (792). Conventional round shaft designs within round delivery sheath **lumens** are also considered acceptable, and in any case, all of these alternative variations apply equally...

...a further delivery sheath/tissue ablation device assembly embodiment, 10 wherein the delivery sheath or **catheter** (792) includes a wall (795) that separate first and second delivery passageways (797, 798). According...

...modes, first and second delivery passageways (797, 798) are adapted to house first and second **guidewires** (740, 750) and respectively engaged first and second delivery members (710, 712). Wall (795) is...

...of the ablation member (714) through the delivery catheter (792) and into the atrium for **ablation**.

More specifically, the wall (795) may be constructed in many alternative modes in order to when only the respective **guidewires** or elongate bodies of the delivery members are housed within those passageways, but also to allow such isolation to be selectively broken such that the **ablation** member can bridge between these same passageways during delivery into the **atrium**.

For example, Figure 7D shows wall (795) to be broken at a separation (796). According...

...passageways (797, 798), wall (795) is constructed to retain its shape to substantially transact the **lumen** formed by delivery **catheter** (792) and maintain the relative isolation and integrity between the two passageways (797, 798). However, where the ablation member (714) is also housed within delivery **catheter** (792), the wall (795) is pushed aside within the delivery **catheter lumen**, as shown in slightly varied modes in Figures 7E-F. It is contemplated by reference...

...795) may be secured at each of its ends to the tubular wall of delivery **catheter** (792), with a break or separation along an intermediate region of the wall within the delivery **catheter lumen**. A further more detailed example of this variation is shown at separation (796) in Figure...

...to break or shear when the ablation member is forced along and within the inner lumen of the delivery catheter .

Figures 70-G also illustrate one particular construction for delivery catheter (792), wherein an outer tubing (793) is disposed over an inner tubing (794). According to this construction, outer tubing (793) may have a first construction and material composition which provides the structural integrity necessary for the delivery catheter (792) to be delivered into the atrium during use. Inner tubing (794) may be therefore chosen merely as a 'liner' in order to provide the wall structure as described, and may be one extrusion or tubing (as shown in the Figures), or may be two separate tubings that are adjoined in a manner resulting in the desired passageway and wall construction for construction of the inner tubing (794), such as by designing a separation into the tubing extrusion or formation itself, or may be post-processed, such as by cutting or scoring the desired separation or frangible portion after formation of the tubing. In one particular embodiment for inner tubing (794), a thin-walled polymer is used, where may or may not be the same polymer used for outer tubing (793), and in the latter case may be for example a thin-walled fluoropolymer lining...

...Still further, one uniform wall construction may also be a suitable substitute for the outerliner tubing variation just described by reference to the particular, exemplary embodiment in the Figures.

The modes for the delivery catheter (792) variously shown throughout Figures 7A-G are believed to be highly desirable for use...

...should be apparent to those skilled in the art, however, that the above-described delivery catheter or sheath construction with a frangible or separated wall can readily be applied in other...

...separate guidewire tracking member (846), which serves as the second delivery member (812), wherein the guidewire tracking member is adapted to slideably engage and track over a guidewire (850) as an anchor for the second end portion (820) of ablation member (814). This assembly is further modified in Figure BB wherein the guidewire tracking member (834) of the first delivery member (810) extends along only a distal portion...

...length. Also encompassed within this embodiment, but not shown in Figure BB, is that the guidewire tracking member (846) of the second delivery member (812) extends along only a distal portion of delivery member (812), such that guidewire (850) is only engaged along a portion of this delivery member's length.

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...8C and 8D further modify the previous embodiments, to include the coaxial engagement of the guidewire tracking members for both first and second delivery members and the ablation member. In this a second guidewire tracking member (846) over a second wire (850). In Figure 8C, the guidewires are engaged along substantially the entire length of the guidewire tracking members. In contrast, in Figure 8D, the guidewires are only engaged along a distal portion of the guidewire tracking members.

10 The tissue ablation assembly of Figure 9 includes a first delivery member (910) with two passageways (936, 976). Passageway (936) ends in a distal guidewire port (938) and forms guidewire tracking member (934)

over a **guidewire** (940) as a first anchor. Passageway (976) terminates distally in a distal port (978) located proximally of distal **guidewire** port (938). Ablation member (914) is slideably engaged within passageway (976) as similarly described for...

...Figure 9 further includes a passageway (948) running its length which tracks over a second **guidewire** (950) thereby providing a second anchor.

In the tissue ablation assembly shown in Figure 10A...

...O 082) and a second end portion (1 083), both extending along a delivery sheath **lumen** (1 092) in a side-by-side arrangement. A first passageway (1 076) extends...

...adjacent left superior pulmonary vein ostium (102). The simplicity of this design allows for two **guidewire** tracking members over first and second **guidewires** (1040,1050) and provides anchors for both ends of ablation member (1014) along the length of tissue to be ablated.

It is further contemplated (shown in shadow), that another **guidewire** (1045) may exit another part (1081) in the elongate member (10091, at or adjacent to...

...additional vertical ablation element (1015) is provided, such that the ablation element (1015) spans the **linear** distance between the superior and inferior left pulmonary vein ostia. Thus, one of skill in...

...that further modification of the ablation assembly shown in Figure 9A, to include an additional **guidewire** and additional ablation elements, may facilitate the induction of a four-sided closed ablation **lesion** connecting the four pulmonary vein ostia; the right inferior pulmonary vein ostium (104) is also pictured. Referring to Figure 1013, the ablation assembly is modified such that the **guidewires** are only engaged along a distal portion of the elongate body (1009).

Figures 10C-D a **guidewire** tracking member (1046) extending proximally in a side-by-side arrangement in parallel with a **guidewire** tracking member (1034)

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of a delivery member (1010) along the delivery...

...1039) such that each shaped region is adapted to engage a vessel extending from an **atrial** wall while the ablation element is engaged along a length of **atrial** wall tissue extending between the vessels' ostia. Figure 100 is similar to the assembly shown in Figure 10C, except showing the first and second **guidewire** tracking members (1034,1046) to extend along only a distal region of the respective end...

...O 1 76) extending along a first delivery member (11 10) that further includes a **guidewire** tracking member (1 134) slideably engaged over a **guidewire** (1 140), and also shows a...

...adapted, as shown in Figure 11 B, to be secured to a length of **atrial** wall tissue from a predetermined location when the **ablation** member (1 14) is anchored by the **guidewire** (1 140) at or adjacent to the predetermined location. The anchoring may optionally be enhanced...

...and 13A-E show various specific embodiments of an ablation assembly which utilizes both a **linear** ablation member (1214) and a circumferential ablation element (1217). These ablation elements (1214,1217) may...

...In an exemplary made, as illustrated in Figure 12, the ablation member (1214) has a **linear** configuration and the circumferential ablation element (1217) utilizes an acoustic energy source that radially emits a collimated energy beam in a circumferential pattern. The present **linear** and circumferential ablation elements (1214,1217) have particular utility in connection with fanning **linear** and circumferential **lesions** along a posterior wall of the left atrium and within or about one of the...energy driver (1 273) to emit a circumferential and longitudinally collimated ultrasound signal. The **linear** ablation member (1214) is operated by an actuator (1272).

The use of acoustic...

...to a large amount of current. For example, a collimated ultrasonic transducer can.

form a **lesion**, which has about a 1.5 mm width, about a 2.5 mm diameter **lumen**, such as a pulmonary vein, and of sufficient depth to form an effective conductive block. It is believed that an effective conductive block can be formed by producing a **lesion** within the tissue that is transmural or substantially transmural. Depending upon the patient, as well as the location within the pulmonary vein ostium, the **lesion** may have a depth of 1 millimeter to 10 millimeters. It has been observed that the collimated ultrasonic transducer can be powered to provide a **lesion** having these parameters so as to form an effective conductive block between the pulmonary vein...more detail, Figures 13A-C variously show the elongate body section (1309) to include a **guidewire lumen** (1336), an inflation **lumen** (1385), and an electrical lead **lumen** (1375). The ablation device, however, can be of a self steering type rather than an over-the-wire type device, as noted below.

Each **lumen** extends between a proximal port (not shown) and a respective distal port, which distal parts are shown as a distal **guidewire** port (1338) for the **guidewire lumen** (1336), a distal inflation port (1387) for the inflation **lumen** (1385), and the distal lead port (1388) for electrical lead **lumens** (1375). Although the **guidewire**, inflation and electrical lead **lumens** are generally arranged in a side-by-side relationship, the elongate body section (1309) of the distal end portion (1380) can be constructed with one or more of these **lumens** arranged in a coaxial relationship, or in any of a wide variety of configurations that...

...terminates in a distal tip. The inner member (1308) forms the distal region for the **guidewire lumen** (1336) beyond the inflation and lead SUBSTITUTE SHEET (RULE 26) parts, and also provides a...

...elongate body section (1309) which is believed to be suitable for use in transeptal left **atrial ablation procedures** is as follows. The elongate body (1309) itself may have an outer diameter provided within...

...about 10 French, and more preferably from about 7 French to about 9 French. The **guidewire lumen** preferably is adapted to slideably receive **guidewires** ranging from about 0.010 inch to about 0.038 inch in diameter, and preferably is adapted for use with **guidewires** ranging from about 0.018 inch to about 0.035 inch in diameter. Where a 0.035 inch **guidewire** is to be used, the **guidewire lumen** preferably has an inner diameter of 0.040 inch to about 0.042 inch. In addition, the inflation **lumen** preferably has an inner diameter of about 0.020 inch in

order to allow for the viscosity of inflation medium used, length of the **lumen** , and other dynamic factors relating to fluid flow and pressure.

In addition to providing the requisite **lumens** and support members for the ultrasound transducer assembly, the elongate body section (1309) of the...

...and transducer (1323) may be placed within the pulmonary vein ostium in a percutaneous transluminal **procedure** , and even more preferably in a transeptal **procedure** as otherwise herein provided. Therefore, the distal end portion (1380) is preferably flexible and adapted to track over and along a **guidewire** seated within the targeted pulmonary vein. In one further more detailed construction which is believed...

...ablation region.

At least a distal portion of the delivery member (1310) tracks over a **guide wire** (1340). Notwithstanding the specific device constructions just described, other variations of the delivery member are also contemplated. For example, while the illustrated mode is shown as an 'over-the-wire' **catheter** construction, other guidewire tracking designs may be suitable substitutes, such as, for example, **catheter** devices which are known as 'rapid exchange' or 'monorail' variations wherein the **guidewire** is only housed coaxially within a **lumen** of the **catheter** in the distal regions of the **catheter** . In another example, a deflectable tip design may also be a suitable substitute and which...

...the transducer assembly into the desired location for ablation. Further to this latter variation, the **guidewire lumen** and **guidewire** shown in Figure 13A may be replaced with a 'Pullwire' **lumen** and associated fixed pullwire which is adapted to deflect the **catheter** tip by applying tension along varied stiffness transitions along the **catheter** 's length. Still further to this pullwire variation, acceptable pullwires may have a diameter within...interior chamber is fluidly coupled to a pressurizable fluid source (not shown) via the inflation **lumen** (1387). In addition to the inflation **lumen** (1385), the electrical lead **lumen** (1375) also communicates with the interior chamber of expandable balloon (1384) so that the...

...the material elongates upon application of pressure and takes on the shape of the body **lumen** or space when fully inflated. Suitable balloon materials include elastomers, such as, for example, but...

...inflated shape (i.e., pre-shaped) to generally match the anatomic shape of the body **lumen** or space in which the balloon is inflated. For instance, as described below in greater...

...more detailed construction which is believed to be suitable for use in most conduction block **procedures** in the region of the pulmonary veins, the balloon is adapted to expand under a...plurality of segments. For instance, the transducer applicator can be formed by a plurality of **tube** sectors that together form an annular shape. The generally annular shape can also be formed...

...about 5 mm to 10 mm. A transducer accordingly sized is believed to form a **lesion** of a width sufficient to ensure the integrity of the formed conductive block without undue...2 mm generates acoustic power levels approaching 20 Watts per centimeter radiator or greater within **myocardial** or vascular tissue, which is believed to be sufficient for **ablation** of tissue engaged by the outer balloon for up to about a 2 cm outer...

...by reference numeral (1235), for the circumferential ablation element (1223) are routed through the lead **lumen** (1275) of the first delivery member (1210), while the wire leads or lead set (1237) for the **linear** ablation element (1214) are routed through one or more wire lead **lumens** that extends through the **linear** ablation member (1 214) and through the second delivery member 0 212). The separation of **lumen**, in which configuration the leads must be well insulated when in close contact. Other configurations for leads are therefore contemplated. For example, a **coaxial cable** may provide one cable for both leads which is well insulated as to inductance interference...

...leads may be communicated toward the distal end portion of the elongate body through different **lumens** which are separated by the **catheter** body.

Still with reference to Figure 1 2, the leads of the lead sets (11 237) for the **linear** ablation element (1 214) are coupled to an ablation actuator (1272), which is configured in...

...current, a monitoring circuit, and a control circuit. The current source is coupled to the **linear** ablation element (1214) via the lead set (1237), and to a ground patch (not shown...

...or more sensors (e.g., temperature or current sensors) which monitor the operation of the **linear** ablation element (1214). The control circuit is connected to the monitoring circuit and to the...

...in order to adjust the output level of the current driving the electrodes of the **linear** ablation element (1214) based upon the sensed condition (e.g., upon the relationship between the...is ablated.

With reference to Figure 13E, the transducer (1323) also can be sectorized by **scoring** or notching the outer.

transducer electrode and part of the central layer along **lines** parallel to the longitudinal axis L of the transducer (1323).

A separate electrical lead connects...

...of the ultrasonic beam around the transducer, and vary the degree of heating (i.e., **lesion** control) in the angular dimension. Again the leads for each sector may be routed through different **lumens** of the two delivery members.

The ultrasound transducer just described is combined with the overall... between the splines, thereby minimizing damping affects from the coupling of the transducer to the **catheter**. The stand-off (1341) is inserted within the inner hollow cavity (1 347) of the...

...from the interior of the balloon. Again, any of a variety of coatings, sheaths, sealants, **tubings** and the like may be suitable for this purpose, such as those described in U...

...available commercially from Epoxy Technology, or Tracon FDA.

An ultra thin-walled polyester heat shrink **tubing** or the like then seals the epoxy coated transducer.

Alternatively, the epoxy covered transducer, inner member and standoff

can be instead into a tight thin wall rubber or plastic **tubing** made from a material such as Teflon", polyethylene, polyurethane, silastic or the like. The **tubing** desirably has a thickness of 0.0005 to 0.003 inches.

When assembling the ablation device assembly, additional epoxy is injected into the **tubing** after the **tubing** is placed over the epoxy coated transducer. As the **tube** shrinks, excess epoxy flows out and a thin layer of epoxy remains between the transducer and the heat shrink **tubing**. This layer protects the transducer surface, helps acoustically match the transducer to the load, makes...

...air backing.

Although not illustrated in Figure 13A in order to simplify the drawing, the **tubing** extends beyond the ends of transducer and surrounds a portion of the inner member on...

...transducer. A filler (not shown) can also be used to support the ends of the **tubing**. Suitable fillers include flexible materials such as, for example, but without limitation, epoxy, TeflonO tape and the like.

Further to known ablation **catheter** devices and **methods** of the type just summarized above, early disclosures of such ablation **catheter** treatments include emitting direct current (DC) from an electrode on the distal end of a **catheter** in order to ablate the targeted tissue believed to be the focus of a particular **arrhythmia**. However, more recently, devices and **procedures** instead use radio frequency (RF) current as the energy source for tissue ablation, as disclosed **catheter**-based ablation

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**procedures** are disclosed in the following references: U.S. Patent No. 5,147,355 to Friedman...

...embodiments of the invention and variations thereof have been described in detail, other modifications and **methods** of use will be readily apparent to those of skill in the art. Accordingly, it...

#### Claim

... source. 1 5 16. The assembly of claim 1, wherein a vessel extends from the **atrium** and has a vessel wall, and wherein the assembly further comprises a circumferential **ablation** member along the distal end portion of at least one of the delivery members and which includes a circumferential **ablation** member that is adapted to ablate a circumferential path of tissue located along the vessel wall or along the **atrial** wall and surrounding the vessel.

17 The assembly of claim 16, further comprising:  
a first...SUBSTITUTE SHEET (RULE 26)

. The assembly of claim 18, wherein a vessel extends from the **atrium** and has a vessel wall, and the assembly further comprises a circumferential **ablation** member along the distal end portion of at least one of the delivery members and which includes a circumferential **ablation** member that is adapted to ablate a circumferential path of tissue located along the vessel wall or along the **atrial** wall and surrounding the vessel.

36 The assembly of dim 35, further comprising:  
a first...distal end portion of the first delivery member and which is adapted to secure the **ablation** element to the first predetermined

location along the **atria** [ wall.

42 The assembly of claim 41, wherein the first anchor comprises a tracking member...a current source.

48 The assembly of claim 37, wherein a vessel extends from the **atrium** and has a vessel wall, and the assembly further comprises a circumferential **ablation** member along the distal end portion of at least one of the delivery members and which includes a circumferential **ablation** member that is adapted to ablate a circumferential path of tissue located along the vessel wall or along the **atrial** wall and surrounding the vessel.

49 The assembly of claim 48, further comprising:  
SUBSTITUTE SHEET...source. 1 5 60. The assembly of claim 50, wherein a vessel extends from the **atrium** and has a vessel wall, and further comprises:  
a circumferential **ablation** member located along the distal end portion of the delivery member and having a circumferential **ablation** element which is adapted to ablate a circumferential path of tissue located along the vessel wall or along the **atrial** wall and surrounding the vessel.

61 The assembly of claim 50, wherein a vessel extends from the **atrium** and has a vessel wall, and further comprising:  
a circumferential **ablation** member located along the second end portion of the **ablation** member and having a circumferential **ablation** element which is adapted to couple to an **ablation** actuator and also to couple to and **ablate** a circumferential path of tissue located along the vessel wall or along the **atrial** wall and surrounding the vessel.

62 A tissue **ablation** device assembly adapted to form a conduction block along a length of tissue between first...a current source.

73 The assembly of claim 62, wherein a vessel extends from the **atrium** and has a vessel wall, and further comprising:  
a circumferential **ablation** member along the distal end portion of at least one of the first and second...

...A tissue **ablation** device assembly for forming a pattern of conduction blocks including a circumferential **lesion** and also a **linear** **lesion** in **cardiac** tissue in a patient comprising: first and second delivery members, each delivery member including a...

...region of tissue surrounding the distal end portion of the first delivery member, and a **linear** **ablation** member comprising a **linear** **ablation** element and which is coupled to the distal end portion of the first delivery...

...element and also to the distal end portion of the second delivery member.

76 A **method** of forming a conduction block along a length of tissue between first and second...length of tissue with the **ablation** element to thereby form the conduction block.

77 The **method** of claim 76, wherein prior to securing the **ablation** element, the **method** further comprises the step of guiding the distal



308

end portion of at least one of...

...second predetermined locations by manipulating the proximal end portion of the delivery member.

78 The **method** of claim 77, wherein the step of guiding is facilitated by visualizing a radiopaque marker on the distal end portion of the delivery member under X-ray.

79 The **method** of claim 77, wherein the guiding step further comprises adjusting the length of the ablation...

...within a passageway

1 0 in at least one of the delivery members.

80 The **method** of claim 76, wherein the step of securing at least one of the first and second anchors comprises sliding a tracking member over a guide member.

81 The **method** of claim 76, wherein the step of securing at least one of the first and...

...from a radially collapsed condition to a radially expanded condition. 1

5 82. The **method** of claim 76, wherein actuating the ablation actuator results in heating of the ablation element.

83 The **method** of claim 76, wherein actuating the ablation actuator results in energizing an ultrasound emitter.

84 The **method** of claim 76, wherein ablating the length of tissue further comprises ablating a circumferential path of tissue located within a pulmonary vein ostium.

85 A **method** of forming a conduction block along a length of tissue between first and second predetermined...

...length of tissue with the ablation element to thereby form the conduction block.

86 The **method** of claim 85, wherein prior to securing the ablation element, the **method** further comprises the step of manipulating the proximal end portion of the delivery member. 41

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The **method** of claim 86, wherein the step of guiding is facilitated by visualizing a radiopaque marker on the distal end portion of the delivery member under X-ray.

88 The **method** of claim 86, the guiding step further comprises adjusting the length of the ablation member...

...member engaged within the passageway in at least one of the delivery members.

89 The **method** of claim 85, wherein the step of securing the ablation element between first and second...

...externally of the body to controllably position the second delivery member. 1 0 90. The **method** of claim 89, wherein the step of securing the ablation element further comprises anchoring at...

...first and second delivery members to the respective first and second predetermined locations.

91 The **method** of claim 90, wherein the anchoring of at least one of the first and second...

...sliding the delivery member over a guide member engaged in the respective passageway.

92 The **method** of claim 90, wherein anchoring of at least one of the first and second delivery...

...an expandable member from a radially collapsed condition to a radially expanded condition.

93 The **method** of claim 85, wherein actuating the ablation actuator results in heating of the ablation element.

94 The **method** of claim 85, wherein actuating the ablation actuator results in energizing an ultrasound emitter.

95 The **method** of claim 85, wherein ablating the length of tissue further comprises ablating a circumferential path of tissue located within a pulmonary vein ostium.

96 A **method** of forming a conduction block along a length of tissue between first and second predetermined...

...first delivery member proximally of the distal part; introducing a second delivery member into the **atrium**, the second delivery member having a proximal end portion and a distal end portion; providing an **ablation** member with a first end portion that is slideably engaged with an adjustable position within...length of tissue with the ablation element to thereby form the conduction block.

97 The **method** of claim 96, wherein prior to securing the ablation element, the **method** further comprises the step of guiding the distal end portion of at least one of...

...second predetermined locations by manipulating the proximal end portion of the delivery member.

98 The **method** of claim 97, wherein the step of guiding is facilitated by visualizing a radiopaque marker on the distal end portion of the delivery member under X-ray.

99 The **method** of claim 96, wherein the step of securing the ablation element further comprises anchoring at...

...first and second delivery members to the respective first and second predetermined locations. 100. The **method** of claim 99, wherein the anchoring of at least one of the first and second delivery members 0 comprises sliding a tracking member over a guide member. 101. The **method** of claim 99, wherein the anchoring of at least one of the first and second...

...an expandable member from a radially collapsed condition to a radially expanded condition. 102. The **method** of claim 96, wherein actuating the ablation actuator results in heating of the ablation element. 103. The **method** of claim 96, wherein actuating the ablation actuator results in energizing an ultrasound emitter. 104. The **method** of claim 96, wherein ablating the length of tissue further comprises ablating a circumferential path of tissue located within a pulmonary vein ostium.

105. A **method** of forming a conduction block along a length of tissue between first and second predetermined...length of tissue with the ablation element to thereby form the conduction block. 106. The **method** of claim 105, wherein the step of securing the ablation element further comprises sliding at least one tracking member over a guide member. 107. The **method** of claim 106, wherein the step of securing the ablation element further comprises advancing first...

...engaged within first and second pulmonary veins, also respectively. 43  
 SUBSTITUTE SHEET (RULE 26)  
 . The **method** of claim 105, wherein the step of securing at least one end portion of the...

...of a vessel extending from the atrium. 109. The method of claim 105 additionally comprising **ablating** a circumferential path of tissue located along an area where a vessel extends from the **atrium**. 110. A **method** of forming a conduction block along a length of tissue between first and second predetermined...

...portion  
 and a distal end portion;  
 110 introducing a second delivery member into the **atrium**, the second delivery member having a proximal end portion and a distal end portion;  
 providing an **ablation** member with a first end portion engaged to the distal end portion of the first...

...length of tissue with the ablation element to thereby form the conduction block. 111. The **method** of claim 110, wherein at least one of the first and second delivery members are secured by anchoring to the respective first and second predetermined locations. 112. The **method** of claim 111, wherein the anchoring of at least one of the first...

...member over a guide member engaged within a vessel extending from the atrium. 113. The **method** of ...an expandable member from a radially collapsed condition to a radially expanded condition. 114. The **method** of claim 110, wherein the step of controllably positioning and securing is facilitated by visualizing...

...marker on the distal end portion of the delivery member under X-ray. 115. A **method** for treating left atrial **arrhythmia**, comprising: introducing first and second delivery members into the left atrium, each delivery member including...

...vein extends from a posterior left atrium wall of the left atrium;  
 providing a linear **ablation** element having a first end portion engaged to the distal end portion of the first...

...second end portion engaged to the distal end portion of the second delivery member, the **linear** ablation element being coupled to a second ablation actuator,  
 positioning the circumferential ablation member along...

...end portion of the second delivery member at the predetermined location, such that the **linear** ablation element is positioned between the pulmonary vein ostium and the predetermined location; actuating the first and second ablation actuators to energize the circumferential and **linear** ablation elements;

ablating the circumferential region of tissue with the circumferential ablation element and ablating a length of tissue with the **linear** ablation element to thereby form a pattern of contiguous 5 conductive blocks.

116. A tissue ablation **system** , comprising:

an ablation member with a first end portion, a second end portion, and an

...

22/3,K/59 (Item 59 from file: 349)  
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**MAPPING AND ABLATION CATHETER WITH INDIVIDUALLY DEPLOYABLE ARMS AND METHOD**

**CATHETER D'ABLATION ET DE CARTOGRAPHIE COMPRENANT DES BRAS A DEPLOIEMENT INDIVIDUEL, ET PROCEDE ASSOCIE**

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**MAPPING AND ABLATION CATHETER WITH INDIVIDUALLY DEPLOYABLE ARMS AND METHOD**

**CATHETER D'ABLATION ET DE CARTOGRAPHIE COMPRENANT DES BRAS A DEPLOIEMENT INDIVIDUEL, ET PROCEDE ASSOCIE**

Main International Patent Class: A61B-005/04

Fulltext Availability:

Detailed Description

Claims

English Abstract

A **catheter** comprising a flexible elongate tubular member (22) having proximal and distal extremities. A deflection tip...

...and has a curved deflecting surface (29). The flexible elongate member has a plurality of **lumens** (26) therein extending through the distal extremity of the flexible elongate member and opening onto...

...surface of the deflecting tip. A plurality of arms (41) are slidably mounted in the **lumens**. Each of the arms has a plurality of electrodes (57) spaced-apart longitudinally thereon. A...

French Abstract

**Catheter** comprenant un element tubulaire allonge et flexible (22) a extremités proximale et distale. Une pointe...

Detailed Description

**MAPPING AND ABLATION CATHETER WITH INDIVIDUALLY DEPLOYABLE ARMS AND METHOD**

In U.S. Patent No. 5,156,151 there is disclosed a basket-like construction...the basket construction. There is therefore a need for a new and improved type of **catheter** construction which will overcome these difficulties.

In general, it is an object of the present invention to provide a **catheter** for mapping and ablation which has

individually deployable arms and a **method** for utilizing said individually deployable arms for mapping and ablation.

Another object of the invention is to provide a **catheter** of the above character in which the individually deployable arms have distal extremities which are curved.

Another object of the invention is to provide a **catheter** of the above character in which the distal extremities are curved into pigtails to prevent **catheter** of the above character having arms with an element disposed therein having a shape-memory.

Another object of the invention is to provide a **catheter** of the above character in which each of the arms is provided with an element having a shape-memory.

Another object of the invention is to provide a **catheter** of the above character in which the individually deployable arms can be deployed to encompass...

...forming the chamber of the heart.

Another object of the invention is to provide a **catheter** of the above character in which the individually ...to fit hearts of different sizes.

Another object of the invention is to provide a **catheter** of the above character having deployable arms which have a stiffness profile that can be adjusted.  
Another object of the invention is to provide a **catheter** of the above character in which the stiffness of the arms can be adjusted by...

...supplied to the shape-memory elements.

Another object of the invention is to provide a **catheter** of the above character in which a deflection tip is provided for deflecting the arms in direction proximally and outwardly from the distal extremity of the **catheter**.

Another object of the invention is to provide a **catheter** of the above character in which the tip deflector is expandable to provide a larger...

...area for  
deflecting the deployable arms.

Another object of the invention is to provide a **catheter** of the above character having a control mechanism by which the individually deployable arms can a symmetric view showing a **catheter** having individually deployable arms incorporating the present invention.

FIG. 2 is a side elevational view partially in cross section showing the hand-held control device forming a part of the **catheter** which is utilized for operating the individually deployable arms.

FIG. 3 is a cross-sectional view taken along line 3-3 of FIG. 2.

FIG. 4 is a cross-sectional view of the distal extremity of a **catheter** shown in FIG. 1 showing one of the individually deployable arms being deployed.

FIG. 5 is a cross-sectional view taken along line 5-5 of FIG. 4.

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 4.

FIG. 7 is an enlarged detail view of one of the deployable arms of the **catheter**.

FIG. 8 is a cross-sectional view taken along the line 8-8 of FIG. 7.

FIG. 9 is a cross-sectional view taken along the line 9-9 of FIG. 7.

FIG. 10 is a isometric view showing the distal extremity of the **catheter** disclosed in the right ventricle of the heart with all of the arms being deployed...wall forming the right ventricle of the heart.

FIG. 11 is another embodiment of the **catheter** incorporating the present invention partially in cross section in which an expandable deflection tip is...

...shown in an unexpanded form.

FIG. 12 is a cross-sectional view looking along the line 12-12 of FIG. 11.

FIG. 13 is a cross-sectional view looking along line 13-13 of FIG. 11.

FIG. 14 is a view similar to FIG. 11 but showing the expandable deflection tip in an expanded form.

In general, the **catheter** incorporating the present invention is comprised ...extremity and has a curved deflecting surface. The flexible elongate member has a plurality of **lumens** extending through the distal extremity of the flexible elongate member and an opening into the...

...deflecting surface of the deflection tip. A plurality of arms are slidably mounted in the **lumens**. Each of the arms has an outer surface on which a plurality of electrodes are arms to be deflected proximally and outwardly from the distal extremity of the **catheter**. Control means is secured to the proximal extremity of the flexible elongate member and is...

...advancing and retracting the arms with respect to the deflectable tip.

More in particular, the **catheter** 21 incorporating the present invention consists of a flexible elongate member 22

which is provided from 3 French to 12 French. The distal extremity 24 of the **catheter** is provided with a plurality of **lumens** 26.

As for example, eight of such **lumens** 26 can be provided which can be rectangular in cross section as shown, the **lumens** 26 are arranged in two groups or sets with one set of four being disposed...

...offset circumferentially to the first set particularly as shown in FIG. 6.

An additional central **lumen** 27 is provided which serves as a **guide wire lumen**. The **lumens** 26 open onto **curved** surfaces 29 which are provided on a deflection tip 31. The deflection tip 31 is a plurality of individually deployable arms 41 are provided in the **lumens** 26 and are slidably mounted therein.

The arms have proximal and distal extremities 42 and...member 66 and are connected to semiconductor chip 61. The tubular members 66 extend through **lumens** 74 circumferentially spaced around the central **lumen** 27 of the flexible elongate tubular member 22 to the proximal extremity 23.

A hand elongate member 22 and forms a part of the **catheter** 21. The control unit 101 consists of a two-part housing 102 which is formed...provided in a computer controlled power supply for supplying energy to the arms 41.

The **catheter** 21 is adapted to accommodate a steerable **guide wire** 136 of a conventional type as for example a .032degrees **guide wire** which extends through a passage 137 provided in the housing 102 and through the central **lumen** 27 in the flexible elongate member 22 and through the deflection tip 31.

Operation and use of the **catheter** 21 may now be described as follows. Let it be assumed that it is desired to perform a mapping **procedure** in the left ventricle of the human heart. The **guide wire** 136 is advanced into the femoral artery of the patient in a conventional manner. The **guide wire** 136 is advanced into the heart 137 as shown in FIG. 11 by advancing the distal extremity of the **guide wire** through the aorta passing it through the aortic valve 138 then to the apex 139 of the left ventricle 141. As soon as the **guide wire** 136 has been properly positioned, the **catheter** 21 is taken and its distal extremity with its tip is advanced over the **guide wire** 136 into the femoral artery and into the same route taken by the **guide wire** so that the deflection tip 31 is brought into contact with the apex 139 of the right ventricle 141. The **guide wire** 136 can then be withdrawn. The arms 41 can then be deployed to bring them...where the mass of the element is greater. The other individual arms 41 of the **catheter** 21 can be individually deployed in the same manner as herein before described. As shown...151 within a single beat of the heart.

It should be appreciated that although the **catheter** has



been described for a mapping operation, it is possible to utilize one of the...When that is the case, the arm opposite those two arms can become a steerable **catheter** and be moved into the ablation site by causing the arm to move one of...

...wall of the heart to attempt to destroy the aberrant pathway which is causing the **arrhythmia** .

It should be appreciated that if necessary, after an **ablation** has been performed and additional mapping is performed with the arms 41 in the same position in the **ventricle** to ascertain whether or not the **ablation** eliminated the site for the **arrhythmia** . If it is found there is still other sites present which are causing **arrhythmias** , the same **procedure** can be utilized until all of the **arrhythmias** are eliminated.

After the ablation has been accomplished, the arms 41 can be de-energized...

...control unit 101 either one at a time or in unison as desired. Thereafter, the **catheter** 21 can ...deflection tip 151 can be formed of a suitable material such as thin wall plastic **tube** of a suitable material such as polyurethane or teflon which has its proximal end 152...by suitable means such as an adhesive (not shown). The distal extremity of the plastic **tube** is swaged inwardly as shown to form an oval shaped opening 156 (see FIG. 12) through which the **guide wire** 136 extends. The **guide wire** 136 of the present invention is provided with an enlarged end portion 136 which also...

...size slightly less than the size of the oval-shaped opening 156 so that the **guide wire** can be withdrawn when it is aligned with the opening 156 as hereinafter described. The thin wall **tube** which ...151 is provided with a weakened region of reduced cross section extending circumferentially around the **tube** substantially equidistant from the proximal and distal extremities 152 and 154.

In operation and use of the **catheter** construction shown in FIGS. 11, 12 and 13, the deflection tip 151 has a diameter...

...elongate member 22 and is advanced in the conventional manner by the use of a **guide wire** 136 first having its distal extremity moved to the desired location and then passing the **catheter** over the same as hereinbefore described. After the **catheter** has been moved to the desired location and it is desired to deploy the arms 41, the expandable deflection tip 151 can be expanded by rotating the **guide wire** 136 so that the oval-shaped tip 136a is rotated into a position which is approximately 90degrees out of alignment with the oval shaped slot 156. The **guide wire** 136 is then pulled to bring the oval-shaped tip portion 136a into engagement with the distal extremity 154 and further pulling of the **guide wire** 136 causes the expandable deflection tip 151 ...to be engaged by the deployable arms 41 as they

are  
pushed out of the **lumens** 26 provided in the flexible  
elongate member 22 as shown in FIG. 14 and as...When all of the arms 41  
have been deployed and the  
desired mapping and ablation **procedures** have been carried  
out as hereinbefore described, the arms can be retracted.

Thereafter, the **guide wire** 136 can be released to permit the  
expandable deflection tip 151 to return to its...  
...so that it returns to its  
original small diameter to permit ready withdrawal of the  
**catheter** after completion of the **procedure**.

It should be appreciated that because of the  
construction of the tip 136a of the **guide wire** it is  
possible to remove the **guide wire** by rotating the **guide wire**  
so that its oval-shaped tip is in alignment with the oval  
s shaped opening...

#### Claim

WHAT IS CLAIMED IS:

1. A **catheter** comprising a flexible elongate tubular member having  
proximal and distal extremities, a deflection tip carried...  
...member and having a curved deflecting surface, said flexible elongate  
member having a plurality of **lumens** therein extending through the  
distal extremity of the flexible elongate member and opening onto the  
curved deflection surface of the deflection tip, a plurality of arms  
slidably mounted in said **lumens** and having distal extremities, each of  
said arms having a plurality of electrodes spaced-apart...to cause the  
arms to deflect proximally and outwardly from the deflection tip.
2. A **catheter** as in Claim 1, wherein each of said arms is provided  
with an element extending...  
...to the elements in the arms for supplying electrical energy to the arms.
3. A **catheter** as in Claim 2, wherein each of the arms ...temperature  
which is substantially less than the body temperature of the patient into  
which the **catheter** is inserted and having a shape-memory which  
corresponds to a pigtail so that when...  
...configuration helping to prevent the distal extremity from becoming  
entangled in the body.
4. A **catheter** as in Claim 1, wherein said flexible elongate member  
has a diameter ...for guiding the arms as they are moved out of the  
flexible elongate member. . A **catheter** for introduction into a chamber  
of the heart formed by a wall comprising a flexible elongate tubular  
member having proximal and distal extremities and having a plurality of  
**lumens** therein extending 5 longitudinally thereof, a plurality of arms  
slidably mounted in said **lumens**, each of said arms having an exterior  
surface and a distal extremity, a plurality ...deflection surface facing  
proximally of the flexible elongate tubular member, said deflection  
surface overlying the **lumens** so that when the arms are slid out of the  
**lumens** they come into engagement with the curved deflection surface and  
are deflected proximally and outwardly...on the housing, push/pull  
elements secured to the control members and extending into the **lumens**  
of the flexible elongate member and being secured to the proximal

extremities of the arms...

...that as the control members are actuated, the arms can be moved out of the **lumens** into engagement with the curved deflection surface so that the electrodes carried by the arms...by the arms and conductors which are connected to the shape-memory elements.

6. A **catheter** as in Claim 5, wherein said push/pull elements are in the form of tubular...

...therein and wherein said conductors extend through said passage in said tubular members.

7. A **catheter** as in Claim 5, wherein the heart is disposed in a body having a ...extending longitudinally of the arm and electrical conducting means connected to said electrodes.

10. A **method** for mapping a chamber of the heart formed ...by a wall carrying electrical potentials and having an apex by the use of a **catheter** having a distal extremity with a deflection tip secured to the distal extremity, and having arms slidably mounted therein and movable into engagement with the deflection tip, the **method** comprising the steps of advancing the distal extremity of the **catheter** into the chamber of the heart so that the distal extremity comes into engagement with urges the arms proximally of the **catheter** and outwardly therefrom, causing the distal extremities of the arms to form pigtails so that...

Set	Items	Description
S1	1127279	ABLAT? OR CRYOABLAT? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR MICROWAV? OR MICRO() (WAVE? OR WAVING) OR ELECTROSURG? - OR ELECTRO?(2N)SURG? OR ELECTRICAL?()ISOLAT?
S2	5127729	ATRIA? OR ATRIU? OR VENTRI? OR CARDI? OR ISTHMUS? OR INTRA- ATRI? OR INTRAVENTR? OR TRANSATRI? OR TRANSVENTR? OR MITRA?(3- N)VALV? OR EPICARD? OR MYOCARD?
S3	565107	FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUT- TER? OR (IRREGULAR? OR RAPID?) () (HEARTBEAT? OR HEART()BEAT?) - OR DISRHYTHM?
S4	2518147	CATHETER? OR CANULA? OR CANNULA? OR CANNULLA? OR CANULLA? - OR LUMEN? OR TUBE? OR TUBING?
S5	363102	ANTENNA? OR (COAXIAL? OR CO()AXIAL?) ()CABL? OR GUIDEWIR? OR GUIDE() (WIRE? OR WIRING)
S6	2531861	USHAP? OR U()SHAP? OR CURV? OR LOOP? OR (180 OR ONE()HUNDR- ED(2N)EIGHTY) ()DEGREE? OR UTURN? OR U()TURN? OR (HAIRPIN? OR - HAIR()PIN) ()TURN? OR JSHAP? OR J()SHAP? OR CSHAP? OR C()SHAP?
S7	283613	PRESHAP? OR PRE()SHAP? OR PREFORM? OR PRE()FORM? OR MEMORY- () (METAL? OR ALLOY?) OR NITINOL? OR MARTEN? OR AUSTEN? OR PRE- DETERMIN?()SHAPE?
S8	9951765	LINE OR LINES OR LINED OR LINEAR? OR LESION? OR CURVILINE? OR SCORE? OR SCORING? OR SCAR? OR ULCER? OR SCORIF?
S9	17476241	METHOD? ?
S10	27687212	SYSTEM?
S11	7866672	PROCESS??
S12	3313765	PROCEDUR?
S13	9137329	TECHNIQUE?
S14	160	S1 AND S2 AND S3 AND S4 AND S5
S15	124	S14 AND S9:S13
S16	160	S14:S15
S17	6	S16 AND S6:S7(10N)S5
S18	6	S16 AND S6:S7
S19	6	S17:S18
S20	5	S19 AND PY<2004
S21	2	RD (unique items)

? show files

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File 99:Wilson Appl. Sci & Tech Abs 1983-2004/Aug  
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File 144:Pascal 1973-2004/Sep W1

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(c) format only 2004 The Dialog Corp.  
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec  
(c) 1998 Inst for Sci Info  
File 481:DELPHEs Eur Bus 95-2004/Sep W1  
(c) 2004 ACFCI & Chambre CommInd Paris  
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13  
(c) 2002 The Gale Group  
?

21/3,K/1 (Item 1 from file: 2)

DIALOG(R) File 2:INSPEC

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**Title:** Catheter microwave ablation therapy for cardiac arrhythmias

**Author(s):** Lin, J.C.

**Author Affiliation:** Dept. of Electr. Eng. & Comput. Sci., Illinois Univ., Chicago, IL, USA

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**Material Identity Number:** A804-1999-004

**Conference Title:** Symposium RF Dosimetry: 25 Years of Progress. To Honor Dr Carl H Durney upon his Retirement

**Conference Date:** 20-21 Oct. 1997 **Conference Location:** Salt Lake City, UT, USA

**Language:** English

**Subfile:** A B

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**Title:** Catheter microwave ablation therapy for cardiac arrhythmias

**Abstract:** Describes three microwave catheter antennas for percutaneous cardiac ablation. A particular design feature of these antennas is that there is no reflected microwave current from the antenna flowing up the transmission line. Thus, it minimizes heating of the coaxial cable. The power reflection coefficients are very low (48 or less) in phantom equivalent materials. These antennas can also serve as bipolar electrodes for sensing endocardiac electrograms. Our studies in dogs, during both cardiopulmonary bypass and closed-chest operations via the femoral vein, have shown microwave energy greater than 200 joules (J) delivered to the heart through a split-tip dipole catheter antenna can produce irreversible block of the heart rhythms. This energy was achieved either by increasing...

...produced an endocardium temperature of about 65 degrees C. We found that the percutaneous, transcatheter microwave system is capable of inducing AV blocks consistently in dogs using the flexible, curved tip, split-tip catheter antenna. In addition, our studies have shown that the width and height of SAR distributions for cap-choke and split-tip catheter antennas are similar for the same antenna length. The cap-slot design had a much longer SAR distribution compared to the others. Moreover, a longer (4 mm) split-tip antenna can also induce larger lesions. These results suggest that it could be possible to ablate a ventricular tachycardia focus using the 4 mm split-tip as well as the cap-slot microwave catheter antennas.

**Descriptors:** biological effects of microwaves ; ...

... cardiovascular system ;

**Identifiers:** microwave catheter antennas ; ...

...percutaneous cardiac ablation ; ...

... coaxial cable ; ...

... cardiopulmonary bypass...

... microwave energy...

...split-tip dipole catheter antenna ; ...

...percutaneous transcatheter microwave system ; ...

...flexible curved tip split-tip catheter antenna ; ...

... antenna length...

...split-tip antenna ; ...

... ventricular tachycardia focus...

...cap-slot microwave catheter antennas ; ...

... catheter microwave ablation therapy...

... cardiac arrhythmias ;  
1999

21/3,K/2. (Item 1 from file: 155)  
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06822171 PMID: 2582389

Atrial and ventricular burst pacing from a coronary sinus catheter :  
relation to position of radiofrequency transmitter.

Marchlinski F E; Eysmann S

Pacing and clinical electrophysiology - PACE (UNITED STATES) May 1985  
, 8 (3 Pt 1) p399-401, ISSN 0147-8389 Journal Code: 7803944  
Contract/Grant No.: 5-T32-HD-07217-03; HD; NICHD; HL00361; HL; NHLBI;  
HL28093; HL; NHLBI

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Languages: ENGLISH

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Record type: Completed

Atrial and ventricular burst pacing from a coronary sinus catheter :  
relation to position of radiofrequency transmitter.

May 1985 ,

A young woman with drug-refractory recurrent supraventricular  
tachycardia was managed by rapid atrial stimulation using a catheter  
positioned in the coronary sinus. During follow-up, radiofrequency  
activation of the pacemaker resulted in burst ventricular and/or atrial  
pacing, depending on the distance of the transmitter's antenna loop  
from the receiver. Current output was directly related to the distance of  
the transmitter's antenna loop from the receiver and ranged from 20 mA  
at a distance of 0 cm from...

... 1 mA at 5 cm. If possible, coronary sinus lead placement should be  
avoided for radiofrequency -activated atrial burst pacing given the  
large current output with direct contact of the transmitter's antenna  
loop to the implanted receiver and the risk for ventricular  
stimulation. Alteration of the spatial relationship between the transmitter  
and receiver can be used to decrease current output and prevent  
ventricular pacing if atrial burst pacing from the coronary sinus is  
desirable.

Descriptors: Electrocardiography; \*Heart Rate; \*Pacemaker, Artificial; \*  
Tachycardia --therapy--TH; Adult; Bundle-Branch Block--physiopathology--PP  
; Coronary Vessels; Electrodes, Implanted; Heart Atria --physiopathology  
--PP; Heart Ventricles --physiopathology--PP; Tachycardia  
--physiopathology--PP



Set	Items	Description
S1	354925	ABLAT? OR CRYOABLAT? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR MICROWAV? OR MICRO() (WAVE? OR WAVING) OR ELECTROSURG? - OR ELECTRO?(2N)SURG? OR ELECTRICAL?()ISOLAT?
S2	534119	ATRIA? OR ATRIU? OR VENTRI? OR CARDI? OR ISTHMUS? OR INTRA- ATRI? OR INTRAVENTR? OR TRANSATRI? OR TRANSVENTR? OR MITRA?(3- N)VALV? OR EPICARD? OR MYOCARD?
S3	56874	FIBRILLAT? OR ARRHYTHM? OR PAROXYSM? OR TACHYCARD? OR FLUT- TER? OR (IRREGULAR? OR RAPID?) () (HEARTBEAT? OR HEART()BEAT?) - OR DISRHYTHM?
S4	475666	CATHETER? OR CANULA? OR CANNULA? OR CANNULLA? OR CANULLA? - OR LUMEN? OR TUBE? OR TUBING?
S5	138417	ANTENNA? OR (COAXIAL? OR CO()AXIAL?) ()CABL? OR GUIDEWIR? OR GUIDE() (WIRE? OR WIRING)
S6	629795	USHAP? OR U()SHAP? OR CURV? OR LOOP? OR (180 OR ONE()HUNDR- ED(2N)EIGHTY) ()DEGREE? OR UTURN? OR U()TURN? OR (HAIRPIN? OR - HAIR()PIN) ()TURN? OR JSHAP? OR J()SHAP? OR CSHAP? OR C()SHAP?
S7	44398	PRESHAP? OR PRE()SHAP? OR PREFORM? OR PRE()FORM? OR MEMORY- () (METAL? OR ALLOY?) OR NITINOL? OR MARTEN? OR AUSTEN? OR PRE- DETERMIN?()SHAPE?
S8	7095335	LINE OR LINES OR LINED OR LINEAR? OR LESION? OR CURVILINE? OR SCORE? OR SCORING? OR SCAR? OR ULCER? OR SCORIF?
S9	1603175	METHOD? ?
S10	9804357	SYSTEM?
S11	4734096	PROCESS??
S12	1807146	PROCEDUR?
S13	1284516	TECHNIQUE?
S14	95	S1 AND S2 AND S3 AND S4 AND S5
S15	90	S14 AND S9:S13
S16	95	S14:S15
S17	28	S16 AND S6:S7
S18	24	S17 AND S8
S19	28	S17:S18
S20	24	S19 AND PY<2004
S21	21	RD (unique items)

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21/3,K/5 (Item 2 from file: 16)  
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**Dynamic'** cardiology market offers innovations, opportunity.  
Simonsen, Michael  
The BBI Newsletter, v25, n5, p121(7)  
May, 2002  
Language: English Record Type: Fulltext  
Document Type: Newsletter; Trade  
Word Count: 4570

(USE FORMAT 7 FOR FULLTEXT)

**Dynamic'** cardiology market offers innovations, opportunity.

TEXT:

...But a number of new product segments also are emerging, including the use of interventional **techniques** to perform tissue engineering on damaged hearts, addressing the approximately 5 million patients in the...

... is vascular sealing devices for closure of the puncture site following a diagnostic or interventional **catheterization procedure**. Although the market is already quite competitive, with three major suppliers having established strong positions...

...offering new and improved product features. The opportunity remains substantial, since fewer than 20% of **procedures** now use the devices. Growth in that segment has slowed as compared to the rapid...

...the sector will remain attractive for suppliers.

Major advances are occurring in interventional treatments for **cardiac arrhythmia**. Use of **ablation techniques** to treat **atrial fibrillation** appears increasingly feasible, and a number of companies, including some that are new to the electrophysiology segment, are pursuing that opportunity. **Cardiac** assist devices represent yet another rapidly developing segment, with new technologies continuing to emerge for temporary support, and long-term **cardiac** support with artificial devices now a reality. The use of information technology is also increasingly pervading the **cardiology** products arena. For example, at the annual scientific sessions of the American College of **Cardiology** (ACC; Bethesda, Maryland), held here in March, Medtronic (Minneapolis, Minnesota) introduced the CareLink **system**, which allows physicians to view data from implantable **cardiac** devices such as defibrillators and pacemakers over a standard telephone **line**, and to remotely consult with other physicians viewing the data via a PC link. Similarly...

...small at present.

Advances in cell transplantation technology

The use of cell transplants to regenerate **cardiac** muscle that has been lost due to **myocardial** infarction represents a significant market opportunity. There are more than 4.6 million patients with...

...stage, although some patients have already received successful transplants. Another application of cell transplantation in **cardiology** is revascularization by stimulating the creation of new blood vessels. As shown in Table 2...

...subsequently implanted at the target site in the heart. Some studies are using cell selection **techniques**, such as purification of a typically heterogeneous population of harvested cells using separation via antibody  
...

...MD, of St. Elizabeth's Medical Center (Boston, Massachusetts) at the ACC conference, the isolation **procedure** usually results in harvest of only about 0.01% of the number of cells needed for treatment, making expansion in culture mandatory. One approach to improving the efficiency of the **procedure** is to transfer genes into the isolated cells that promote growth of the desired cell...

...are unsuitable for percutaneous intervention or bypass surgery, or who have incomplete revascularization after such **procedures**.

Bone marrow stem cells are proving to be one good candidate cell type for inducing...

...well suited to differentiate into vascular cells. Tse has used the Cordis Biosense MyoStar injection **catheter** to inject cells into the left **ventricle** of eight patients with severe, untreatable coronary artery disease who had previously failed all other revascularization options (CAGB, percutaneous intervention, and percutaneous **myocardial** revascularization using laser **techniques**). The **procedure** is relatively complex, involving an average of 16 injections per patient and a **procedure** time of over 200 minutes. Some improvement in ejection fraction has been observed (61% in...

...the effect to develop.

TransVascular (Menlo Park, California) also is actively pursuing applications of its **catheter**-based **system** for cell implantation therapy. The focus of TransVascular's studies is on restoration of contractile units in the heart and also maintaining a favorable **ventricular** geometry. The **technique**, called cellular **cardiomyoplasty**, uses the company's coronary venous **catheter** technology. Advantages include avoidance of shunting of cells away from the target region by blood ...

...to diseased areas of the heart that may not be readily reached via an arterial **catheter**. TransVascular has developed a **technique** for harvesting of progenitor cells from bone marrow, preserving them in bovine collagen gel and then expanding the cells in culture prior to injection. The company's CrossPoint TransAccess **Catheter**, a 2 Fr device, is then used to perform a transvenous puncture to access the target site, and the MicroLume **Catheter**, a 27G microinjection device, is used to deploy a network of cells. Animal studies with...

...Trans Vascular delivery technology are in progress.

A new approach to delivery of cells for **myocardial** regeneration was described at the ACC conference by a group led by Keith March, MD, PhD, of Indiana University's Krannert Institute of **Cardiology** (Indianapolis, Indiana). The **technique** employs retrograde infusion through the coronary venous **system** to allow widespread distribution of cells throughout the **myocardium**. Microspheres manufactured by BioPal (Wellesley Hills, Massachusetts) have been used, along with a neutron activation...

...the infused particles are retained in the heart, and that one-third of the left **ventricle** contained microspheres. Viability of infused cells has been demonstrated via BrdU labeling. As opposed to...

...delivery of cells to regions of the heart that require regeneration, the retrograde infusion **technique** provides a more widespread distribution of cells throughout the **myocardium**, although the distribution is not necessarily uniform. Studies are planned to assess survival of infused cells in infarcted regions of the heart. The **procedure** requires only a

single injection lasting a few seconds, vs. the lengthy **procedure** needed for targeted injection of cells. A standard diagnostic angiography **catheter** can be used for the infusion. A limiting factor at present is obtaining a sufficient...

...needed for therapy remains an open question even for targeted injection approaches. The retrograde infusion **technique** will face a greater challenge in this regard, however, since not all of the infused...  
...the regions requiring regeneration.

The potential market for devices used for cell transplantation therapy in **cardiology** is potentially quite large. Diacrin (Charlestown, Massachusetts), one of the companies developing technology to regenerate **cardiac** tissue for the treatment of **cardiac** disease, estimates a target U.S. patient population of 200,000 per year, representing the...

...most in need of regenerative therapy. Based on costs of comparable existing therapies, a successful **cardiac** cell regeneration technology could sell for as much as \$5,000 per treatment, representing an...

...with congestive heart failure could greatly expand the potential market.  
Expanded peripheral vascular role

While **cardiologists** have generally confined their practice to treating diseases of the heart and coronary arteries, the...

...aortic aneurysm, is also one that has attracted the attention of a growing number of **cardiologists**. For suppliers of stents, devices for the treatment of peripheral vascular disease represent an opportunity to expand their served market, allowing conversion of a large number of **procedures** now performed by vascular surgeons to minimally invasive **techniques**. The treatment of carotid artery stenosis, a condition that can lead to a stroke if not treated, represents a potential market opportunity of approximately 150,000 **procedures** per year in the U.S., based on the number of carotid endarterectomy surgeries performed...

...ACC sessions, carotid endarterectomy was first performed in the early 1950s, and experience with the **technique** resulted in halving of the **procedural** stroke and death rates between the mid-1980s and the mid-1990s. The number of **procedures** has doubled over the past 10 years, indicating that improved outcomes have stimulated use of...

...with carotid stenting, including studies that include the use of embolic protection devices during the **procedure**, indicates that stenting is safer than surgery. Ouriel said he now believes that carotid artery...

...and Medtronic (Minneapolis, Minnesota). Carotid stents typically are based on self-expanding stent technology using **nitinol** or a similar metal, in order to withstand compression forces that are more common in...

...in the coronary arteries. A key ancillary device needed to ensure the safety of the **procedure** is an embolic capture **system**. Those devices are also under development by stent suppliers, as shown in Table 3 on...devices have addressed applications in coronary intervention (e.g., for treatment of patients suffering acute **myocardial** infarction), other versions of the devices are being evaluated for use in carotid interventional **procedures**. For example, Medtronic obtained FDA clearance for the PercuSurge Guard Wire **system** in January for use in saphenous vein graft interventional **procedures**, and it is continuing to evaluate the device for use in carotid stenting **procedures**. There are a total of 26 embolic protection devices under development, according to Gregg Stone, MD, of the **Cardiovascular** Research Foundation (New York). An important characteristic for embolic

protection **systems** is the crossing profile of the device, since an excessive profile can cause dislodgement of embolic particles from the site to be treated before the capture **system** can be deployed. Device designs have continued to evolve to lower-profile versions, with profiles...

...embolization. MedNova (Galway, Ireland) has now progressed to a third generation design for its NeuroShield **system**. As described in a poster presentation at the ACC conference by a group of **cardiologists** from Lenox Hill Heart and Vascular Institute (New York), including Christina Brennan, Gary Roubin, and...

...a study of elderly patients (octogenarians) resulted in reduction in the rate of major pen- **procedural** strokes from 6.8% to zero, and the rate for fatal strokes was reduced from...

...rate to 5.1%. The NeuroShield, as well as the Guardian Occlusion Balloon embolic protection **system** from Rubicon Medical (Salt Lake City, Utah), will be distributed by Abbott Laboratories (Abbott Park...

...White Bear Lake, Minnesota) TRAP filter, contain a hydrophilic coating to facilitate passage through a **lesion** prior to treatment. So far, the results of clinical trials with carotid stents have not...

...by far the most widely used device so far. In a study conducted at the **Cardiovascular** Center Berthannien (Frankfurt, Germany) using a wide variety of stent designs, 66% of all carotid...

...in the medical device sector. One company, Appriva Medical (Sunnyvale, California) exhibited the X-Caliber **System**, designed to help prevent thromboembolic strokes in patients with **atrial fibrillation** who are unable to take coumadin. The **system** employs an ePTFE plug inserted via transcatheter **techniques** to block flow in the left **atrial** appendage, which is the site where clots typically form during **atrial fibrillation**. The plug is inserted via a transseptal puncture, in a **procedure** called Percutaneous Left **Atrial** Appendage Transcatheter Occlusion (PLAATO), and remains in place permanently. At present, Phase I feasibility studies...

...planned. According to the American Heart Association, 2 million individuals in the U.S. have **atrial fibrillation**, and the condition is cited as a principal or contributing cause for over 61,500...

...each year in the U.S., or about 90,000 strokes, are attributable to **atrial fibrillation**.

Vascular brachytherapy is another technology finding applications in peripheral vascular therapy as well as in coronary intervention. Three intravascular brachytherapy **systems** are now available for treatment of in-stent restenosis to help prevent recurrent restenosis, including the Beta-Cath from Novoste (Norcross, Georgia), the CheckMate **system** from Cordis and the Galileo **system** from Guidant. All three were initially introduced for use in the coronary vessels. However, in...

...of promising results with drug-eluting stents for in-stent restenosis prevention, suppliers of brachytherapy **systems** are now actively exploring other applications, such as in the peripheral vessels. Novoste, the current leader in intravascular brachytherapy, has recently initiated the MOBILE trial using its Corona **system**, which investigators find very similar in operation to the coronary Beta-Cath **system**. The company recently filed an IDE application to conduct the BRAVO trial to study uses of the Corona **system** in preventing restenosis in dialysis access grafts, an application that could address up to...

...term growth in the sector. In the electrophysiology arena, devices for

the treatment for atrial **fibrillation**, long recognized as by far the largest potential opportunity in the **ablation** device segment, now appear to be closer to the market. A key breakthrough is the discovery that circumferential **ablation** of conduction channels around the orifices of the pulmonary veins is a very effective treatment for atrial **fibrillation**. Afx (Fremont, California) exhibited a new **microwave** surgical **ablation** device at the ACC conference that can be used to treat atrial **fibrillation**. The existing Afx **ablation** device is placed on the pericardium using a port access **technique**. **Microwave** energy is used to **ablate** tissue in a pattern that mimics the Maize **procedure**. A transcatheter version of the device is under development. Afx is a venture-funded company, and received 510(k) clearance for its FLEX 10 **Ablation** Probe accessory for the Afx **Microwave Surgical Ablation system** in February, including an indication for use in **ablation** of cardiac tissue.

CardiacAssist (Pittsburgh, Pennsylvania) exhibited its new temporary cardiac support **system**, the TandemHeart Percutaneous Ventricular Assist Device (pVAD), at the ACC conference. The company also is...

...to 60% of the heart's pumping ability vs. only about 20% for existing IAPB **systems**. It provides continuous flow using a two- **catheter system** (one placed in the femoral artery, and a second in the left atrium), although there...

...implanted VAD at a fraction of the cost, avoiding the need for two invasive surgical **procedures**.

Another segment of the cardiology device market that continues to attract new entrants is arterial closure devices used to seal the puncture wound following a diagnostic or interventional **procedure**. The market for such products is well established, and is estimated at over \$300 million...

...Vascular Solutions, the QuickSeal from Sub-Q (San Clemente, California), and the EVS Vascular Closure **System** from AngioLink (Taunton, Massachusetts). The D-STAT is a flowable hemostat, employing an injectable solution...

...company's Duett closure device. The Sub-Q QuickSeal is an over-the-wire closure **system** employing a plug of bovine gelatin sponge (Gelfoam) that is applied in an extravascular fashion...

...management of hypertension. Medtronic introduced the CareLink programmer at the ACC exhibition, a newly approved **system** that allows clinicians to review data on implantable cardiac defibrillators remotely in real time. The **system** brings telemedicine technology into the cardiac rhythm management arena by allowing consulting cardiologists to view...

...data over a PC link. A key factor that will determine the success of such **systems** is the level of reimbursement that is available for physicians who provide remote consultation services...

...as the rules governing reimbursement. Reimbursement policy is not yet determined for the Medtronic CareLink **system**. Trends in related areas such as home telemonitoring of heart failure patients indicate that policies...

...cardiologists is telephonic monitoring of blood pressure. Wellness Monitoring (San Ramon, California) demonstrated its BPfone **system** at the ACC meeting. The **system** already is in use by thousands of patients in the UK and Australia, according to...

...Reports showing blood pressure trends over time are generated from data

recorded over the phone line , and can be mailed or faxed to the physician from the Wellness Monitoring data center...

...4.676 billion 11.4%

2006 \$4.936 billion 5.6%

Includes coronary stents, PTCA **catheters** and **guidewires** , guide **catheters** , ancillary devices, wound closure devices and intravascular brachytherapy devices.

Source: The BBI Newsletter  
Table 2

#### Cell Transplantation Technology in Cardiology

Company	Technology
Biocardia (South San Francisco, California)	Helical Infusion <b>Catheter</b> for cell delivery to heart; anchors to wall of vessel to...

...stresses

and obtain precise targeting.  
Universal Deflectable Guide Catheter for controlled guidance of infusion **catheter** to injection site

Bioheart (Weston, Florida)	MyoCell for myocardial infarction; MyoCellCF for heart failure; MyoGene for both conditions; AlloCell uses allogeneic cells for both indications.
-------------------------------	--

Cordis/Biosense (Miami Lakes, Florida)	MyoStar <b>catheter</b> combining NOGA guidance technology with 27G deployable injector needle
--	--

Diacrin	Autologous myocyte...
---------	-----------------------

...University Retrograde coronary venous cell  
Krannert Institute infusion.  
of Cardiology  
(Indianapolis,  
Indiana)

TransVascular (Menlo Park, California)	CrossPoint access <b>catheter</b> . Micro-Lume microinjection <b>catheter</b> for cell implantation via coronary venous injection.
--	--

Company	Development Status
---------	--------------------

Biocardia	Numerous cell types...
-----------	------------------------

...use by numerous  
(Miami Lakes,  
Florida)

researchers and companies for precise targeting of cell delivery **procedures** .



Diacrin  
(Charlestown,  
Massachusetts...

Phase I trial being conducted  
at six sites in U.S.; 13

...Development-Stage Devices for Treatment of Carotid Artery  
Stenosis

Company

Technology

Arteria  
(South San Francisco,  
California)

Parodi Anti-Emboli **System** ;  
uses two balloons to occlude  
both common and external  
carotid artery during  
interventional **procedure** to  
reverse direction of blood  
flow in internal carotid.  
Blood is re-transfused into  
femoral...

...also

under development.

Boston Scientific  
(Natick, Massachusetts)

Carotid Wallstent Monorail  
stent with rapid exchange  
delivery **system** /FilterWire  
EX embolic protection device.

Cordis/J&J  
(Miami Lakes, Florida)

Precise self-expanding  
**nitinol** stent plus H/H Carotid  
**Guidewire** ; .014" wire profile,  
5F crossing profile.  
AngioGuard embolic protection  
device.

Guidant  
(Indianapolis, Indiana)

AccuLink stent; AccuNet  
Protection Device.

Invatec Srl  
(Rocadelle, Italy)

MO.MA double occlusion  
balloon **catheter** ; occludes  
both external and common  
carotid.

Medtronic  
(Minneapolis, Minnesota)

PercuSurge GuardWire  
occlusion balloon;  
self-expanding **nitinol**  
carotid stent with .070" (5F)  
crossing profile and flexible  
10cm distal sheath.

Microvena (White Bear Lake,  
Minnesota)

TRAP NFS Neurovascular Filter;  
**nitinol** braided embolic  
protection device.

Rubicon Medical  
(Salt Lake City, Utah)

Guardian Occlusion Balloon

Company

Development...

EVENT NAMES: 240 (Marketing **procedures** )  
20020501